

Experiences of Small Business Respirator Innovation

Presented at:

NIOSH No-Fit Test Workshop

November 6, 2008

Presented by:

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Breathe Safely, LLC

Experiences of Small Business Respirator Innovation

- **Necessity – the mother of invention**
- **Attempts to Commercialize**
- **Current Questions to Commercialize**
- **Next Steps**

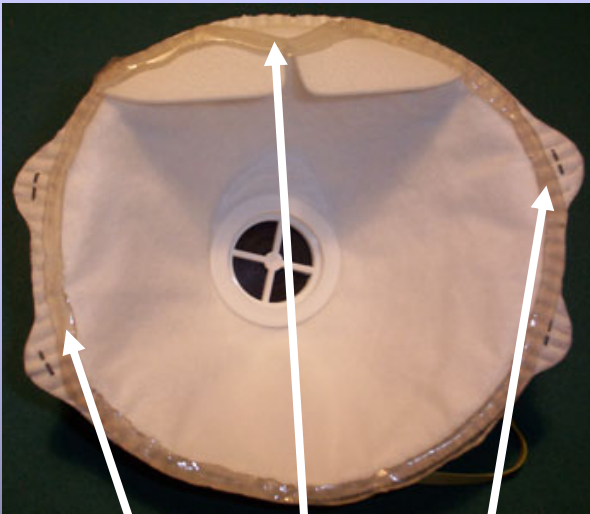
Necessity – the mother of invention



- Semi-Professional motorcycle racer developed a “breath deflector that works” for his own use.
- Adhesive seal at nose bridge and cheeks to assure breath deflection downward
- Patented the concept
 - applied for in '96
 - issued in '98
- PRO-FOG product now commercialized and is widely available.

Necessity – the mother of invention

- Inventor began using N95 FFP in motorcycle paint shop but disappointed in protection
- Applied ***PRO-FOG*** concept to perimeter of N95 FFP
- ***PRO-FOG*** concept “sealed” the respirator to eliminate leakage
- Patent
 - Applied for in January '02
 - Issued in March '06



*Perimeter Bead
of Adhesive Seal*

Attempts to commercialize the “Sealed Respirator”

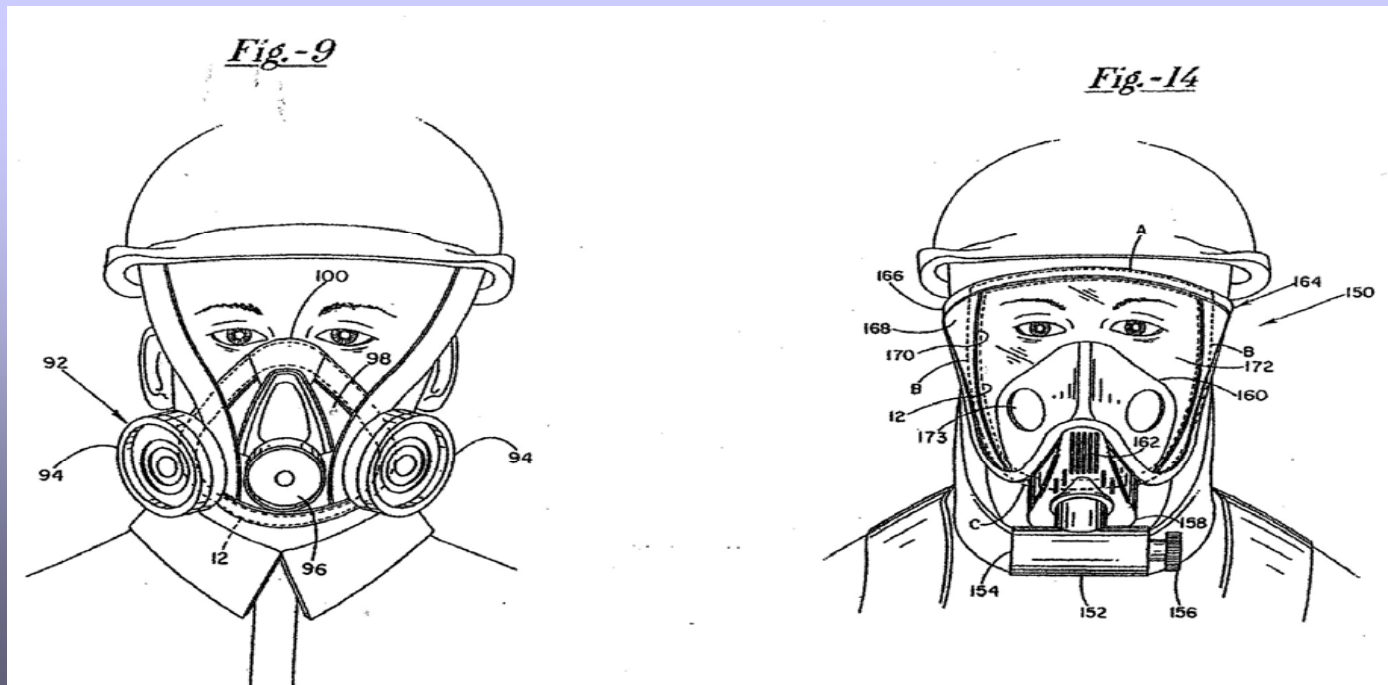
- Performance testing
 - ICS Laboratories



- Tests performed in June 2003
- Identified test subject who could only pass with “sealed” respirator
- Performed standard N95 fit test which limits FF to 200
- Fit factor improvement of “sealed respirator“ not quantified.

Attempts to commercialize the “Sealed Respirator”

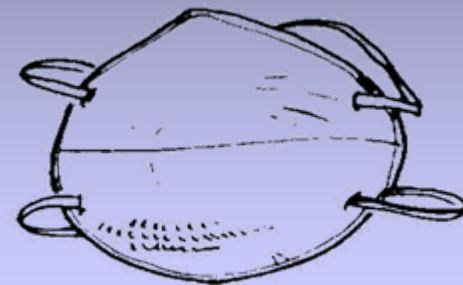
- Contracted with technology broker for assistance
- Patent considered to be valuable intellectual property
- Identified and contacted over 25 candidate manufacturers
 - Interest indicated from 6-8 and samples provided
 - Primary interest from 1 manufacturer



Attempts to commercialize the “Sealed Respirator”

- **Results from the key candidate**
 - **Breathe Safely** modified N95 samples manufactured by the company to include the patented “seal”
 - **Sales & Marketing**
 - Skeptics at first but trial use indicated improved performance
 - Qualitative evaluation
 - **Engineering**
 - Determined that the patented “seal” significantly improved performance
 - Quantified results from fit testing not released.

Attempts to commercialize the “Sealed Respirator”

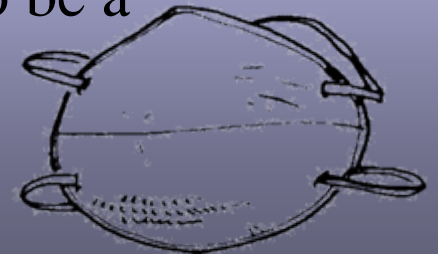


- **Results from the key candidate**
 - **Legal concerns**
 - Review determined very significant performance improvement
 - Introducing a new “sealed” product line made current products appear as having deficient sealing characteristics
 - Introducing “sealed” versions of a current product line inferred current versions are “unsealed” and could be construed as knowingly selling “unsafe” products
 - If the “sealed” concept adopted, it must be on all respirators
 - Implications concerning compliance with current regulations?

Current questions to commercialize the “Sealed Respirator”

- **Licensing & Litigation**

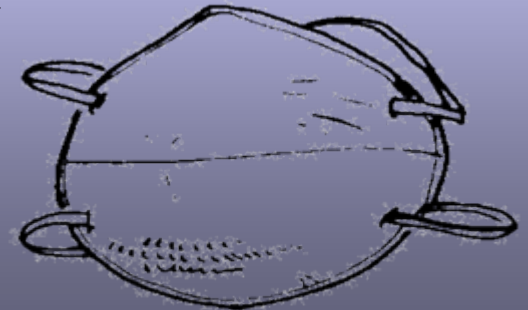
- Is the concern from one manufacturer regarding potential litigation from “sealed” vs. “unsealed” common to other manufacturers?
- If true, does this infer that a new manufacturer without product history would be immune from this type of potential litigation?
- Does exclusive or non exclusive licensing affect above questions?
- Why wouldn't N95 certification continue to be a reasonable defense?



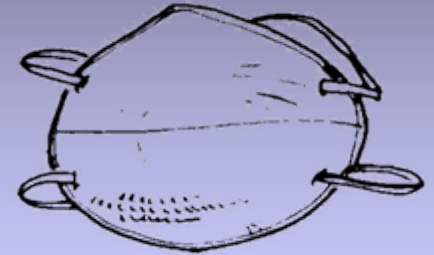
Current questions to commercialize the “Sealed Respirator”

- **Regulations**

- Is the “sealed” respirator concept a candidate for the new TIL standard?
- If tested to the N95 standard today, how long will this be recognized?
- If the “seal” is the only modification to an existing half face respirator, what new approvals are required?
- Can a “seal” be retrofitted to a new respirator and be in or out of any compliance?



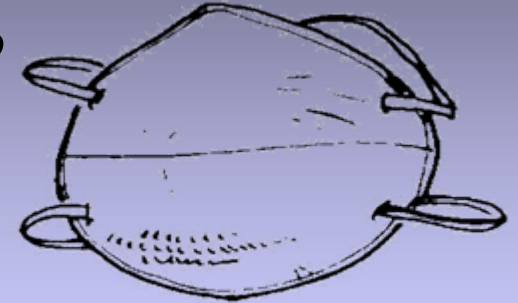
Current questions to commercialize the “Sealed Respirator”



- **Manufacturing**

- N95 certification requires an evaluation of the manufacturing facility. Can an N95 FFP be considered raw material such that the only new evaluation and certification is the “seal” addition process?
- If the above is not acceptable, can an existing manufacturer with an approved facility manufacture as an OEM a “sealed” version of an existing product?
- If the above is not acceptable, and existing manufacturers’ concerns regarding litigation are valid, does this mean the only option is a new facility by a new manufacturer?

Current questions to commercialize the “Sealed Respirator”



- **Application and Deployment**

- If a facility has a “sealed” and “unsealed” version of a respirator, what criteria is used to determine who gets what?
- If a facility decides to switch to “sealed” versions, what should be the disposition of the “unsealed”?
- If a “sealed” version is demonstrated to fit far more face shapes and provide higher levels of protection, does this change training and testing requirements?

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Next Steps

- Continue optimizing seal design.
- Seek out manufacturing partner.
- Seek out research partner to further validate performance of “sealed” respirators.
- Seek out research partner to identifying an optimum level of training and testing for the workplace and the public.



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If you knew the hazard was real, would you want a seal?