

Patent Law

Fall 2020

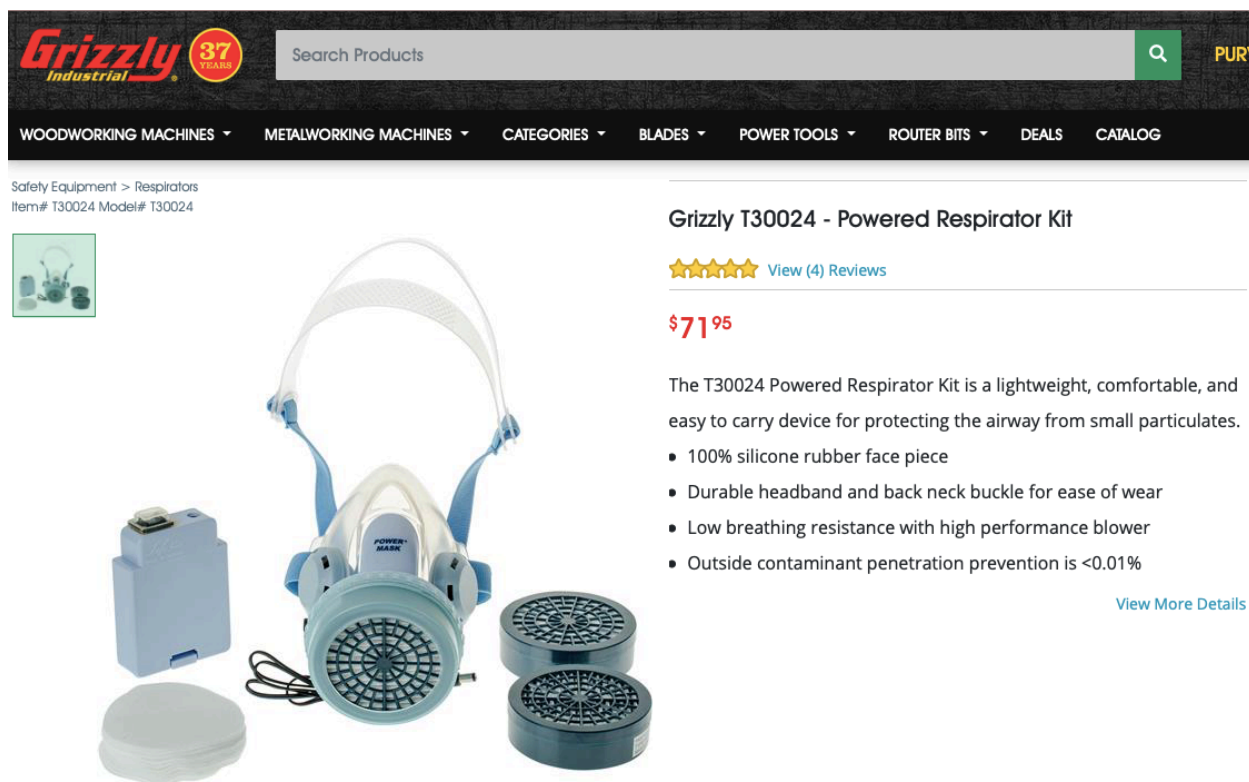
Professors William Fisher and Ruth Okediji

1. This is a four-hour, open-book examination. It will be available for download at 12:01 a.m. EST on December 17. It is due 4 hours after it is downloaded, or by 11:59 p.m. EST on December 17, whichever time is earlier.
2. The exam mode is TAKEHOME. During the exam, you may consult any material you wish. The only thing you may not do is consult in any way with any other person during the exam.
3. The exam contains two questions. Your answer to question #1 may not exceed 2000 words. Your answer to question #2 may not exceed 1500 words. Please use the Answer Separator in Exam4 between your two answers.
4. Your answers to the two questions will be given equal weight when determining your final grade.
5. Exam4 will automatically put your Anonymous ID and word count on the exam copy. Do not write your name on any part of your response. To preserve the anonymity of your response, avoid including any information that would enable the instructor to identify you.

Question #1

Carla is your aunt. For many years, she has worked as a nurse in Green Acres Hospital (GAH) in rural Massachusetts.

Carla's principal hobby is woodworking. Aware of the health hazards of the dust produced by woodworking machinery, Carla always wears a respirator when she is cutting or sanding wood in her shop at home. She has tried several models and has found the one depicted below to be the most effective.



Grizzly T30024 - Powered Respirator Kit

★★★★★ [View \(4\) Reviews](#)

\$71⁹⁵

The T30024 Powered Respirator Kit is a lightweight, comfortable, and easy to carry device for protecting the airway from small particulates.

- 100% silicone rubber face piece
- Durable headband and back neck buckle for ease of wear
- Low breathing resistance with high performance blower
- Outside contaminant penetration prevention is <0.01%

[View More Details](#)

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- 100% silicone rubber face piece
- Durable headband and back neck buckle for ease of wear
- Low breathing resistance with high performance blower
- Outside contaminant penetration prevention is <0.01%
- 0.3 micron filter prevents small wood or metal dust from irritating the airway
- Requires 4 AA batteries (not included)

In March of 2020, GAH began to admit patients infected with the coronavirus. Carla, as the most senior nurse on the staff, was often assigned to care for them. Like many hospitals, GAH had trouble obtaining adequate supplies of personal protective equipment. N95 masks were in especially short supply. Even when such masks were available, Carla found them to be imperfect. No matter how carefully she followed the instructions, some unfiltered air would pass between the

sides of her nose and the edges of the masks when she breathed, potentially exposing her to pathogens. Unsatisfied, Carla began exploring alternatives.

Her first experiment was to wear her Grizzly woodworking respirator (depicted above) when caring for COVID-19 patients. Because the blower in the respirator generated positive pressure, she no longer had to worry that she was breathing unfiltered air. However, she was concerned about the quality of the filters in the Grizzly device. In addition, the respirator frightened some of her patients, prompting her supervisor to discourage its use.

In April, Carla began experimenting (at home in the evenings) with combinations of components that would address the disadvantages of the Grizzly. By May, she had created the following combination:

- a) An adjustable-speed, battery-operated blower (manufactured by 3M, originally developed for PAPR machines), connected to:
- b) A small N95 canister filter, connected to:
- c) A three-foot section of transparent surgical tube, connected to:
- d) A face mask that appeared to be a standard surgical mask, but was actually made of material that was both stiffer and less permeable, connected to:
- e) Another three-foot section of transparent surgical tube, connected to:
- f) A second N95 canister.

She wore the blower on her belt and placed the canisters in a pocket on the inside of her white coat. Images of these components (all commercially available) and a diagram showing how they fit together in her invention appear below.



Roll over image to zoom in

3M PAPR Versaflo Replacement Blower TR-301N+ for Versaflo Powered Air Purifying Respirator TR-300N+

Brand: 3M

Price: **\$472.92** ✓prime & FREE Returns

Thank you for being a Prime member. Get a \$100 Gift Card: Pay \$372.92 upon approval for the Amazon Prime Rewards Visa Card. No annual fee.

- Available as a replacement blower
- Two selectable flow rate options 65 CFM and 72 CFM
- Easytouse and versatile PAPR for particulate environments
- Offers more options and comfort to the user

Specifications for this item

Brand Name	3M
Color	Beige
Ean	0076308942625
Global Trade Identification Number	00076308942625
Height	4.25 inches
Included Components	Personal Protective Equipment
Item Weight	1.27 pounds
Length	9.375 inches
Manufacturer Series Number	TR-301N+

\$472.92


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Qty: 1

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44326

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Roll over image to zoom in

Tygon ND100-65 Medical/Surgical Plastic Tubing, Clear, 3/8" ID x 5/8" OD x 1/8" Wall, 50 feet Length

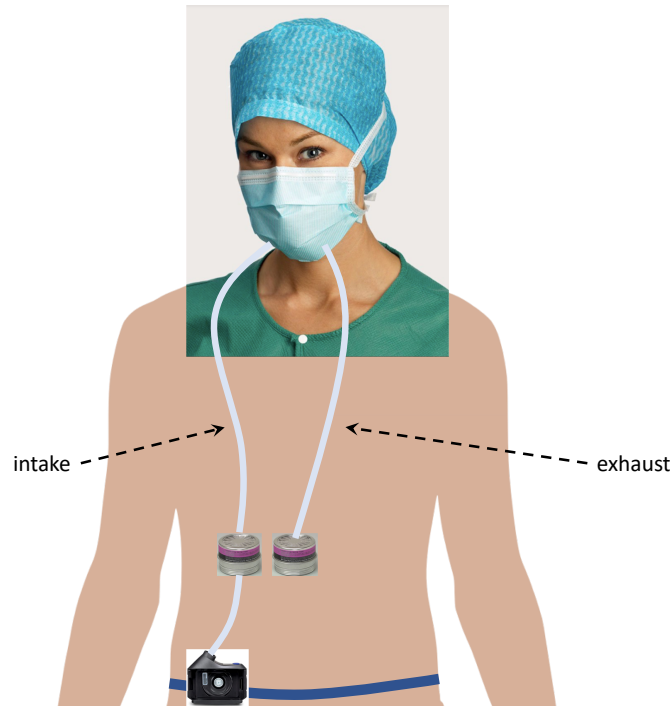
Brand: Tygon

Available with an Amazon Business account and healthcare license.

- Crystal clear for easy visualization of fluid flow
- Ideal for contact with bodily fluids
- Non-DEHP plasticized tubing
- Non-wetting surface permits complete drainage
- Meets USP Class VI criteria and REACH compliant

Specifications for this item

Brand Name	Tygon
Color	Clear
Construction Type	Crystal Clear
For use with what product?	Minimally Invasive Devices, Blood and IV Solutions, Dialysis Equipment, Wound Drainage, Inhalation Equipment, Chemotherapy Drug Delivery, Kidney Dialysis Pumps, Peristaltic Pumps, Catheters
Inside Diameter	3/8 inches
Item Diameter	5/8 inches



Carla's device worked well. The positive pressure inside the mask produced by the blower made it easy for her to breathe and ensured that no unfiltered air leaked into the mask through the gaps beside her nose. The first of the two N95 canisters maximized the probability that the air Carla inhaled was free of viruses, and the second canister protected her patients from germs in her exhalations if she happened to be infected but asymptomatic. The device was light and quiet. And, because most aspects of the device were hidden by her coat, it did not alarm her patients or trouble her supervisor.

In June, the success of the device prompted the physicians and the other nurses in GAH to ask that she make copies for them. Carla obliged, charging each of her colleagues the cost of the components plus a modest premium. Thus far she has sold 20 of these devices. She is considering expanding her business.

In July, LG (a company based in South Korea) announced that it had developed a new mask that, like Carla's invention, combined a blower with N95 filters to enhance protection against viruses. Photographs, taken from the company's press release, appear below.



LG has not yet sold any of these devices. In any event, Carla is not worried that LG's device will undercut the market for her own invention. Its weight, she believes, will make it uncomfortable to wear for long periods, and patients will find it intimidating.

A few weeks ago, you had a Thanksgiving dinner (via Zoom) with members of your extended family. When Carla learned that you had just completed a course on Patent Law, she eagerly requested advice concerning her invention. Specifically, she asked you:

- a) Is my device sufficiently new and useful to enable me to get a U.S. patent on it?
- b) If so, is there a time limit on when I should apply for a U.S. patent?
- c) I've heard that surgeons have trouble getting patents on their inventions; is that a problem for me?
- d) If I obtained a patent and then another company (such as LG) copied my invention, would the law prevent the company from selling its copies in the United States? If not, could the company be forced to pay me a fee?
- e) How would my legal position change if the company's product were similar to mine but not exactly the same?
- f) If I obtained a patent and went into business, which of the various business strategies that you discussed in your course do you think I should employ?
- g) Anything else I should know or do?

You declined to answer Carla immediately, but promised to respond after you had finished studying for your exam. In an essay containing no more than 2000 words, now answer each of Carla's questions. If you need additional information, say what that information is and why it matters.

Question #2

Select one and only one of the following two options:

- (A) You are an intern, working for a member of President-elect Biden's transition team. Biden has asked your employer – who in turn has asked you – for three practicable recommendations concerning how the patent system of the United States could be improved. Draft a memorandum containing no more than 1500 words describing your three recommendations, explaining what defects in the current system they would correct, and explaining why they would not violate any of the international agreements to which the United States is a party.
- (B) Member States of the World Trade Organization (WTO) are considering a proposal from the World Council of Indigenous Peoples (WCIP) to amend the TRIPS Agreement to exclude from patentability inventions for which the unauthorized access and use of traditional knowledge and genetic resources has contributed materially to the claimed invention. The proposal makes three principal arguments: 1) Unauthorized access and use of traditional knowledge violates a number of international treaties, including the Convention on Biological Diversity and the Nagoya Protocol; aligning the international patent regime with other international treaties would promote the global public interest. 2) Allowing patents on inventions based on the unauthorized access and use of traditional knowledge presumptively violates the novelty requirement required by the TRIPS Agreement. 3) The current patchwork approach to the unauthorized access and use of traditional knowledge, with every country adopting its own national law, creates uncertainty for patentees and undermines the longstanding goal of harmonizing patent standards on a global basis.

You have been appointed Special Advisor to the newly elected Director General of the WTO, Dr. Ngozi Okonjo-Iweala. She has asked for your opinion about the proposal. In particular, she wants to know which theories of intellectual property best justify the proposal, whether the principal arguments set forth by the WCIP are persuasive, and what would be the strongest arguments *against* the proposed amendment. Dr. Okonjo-Iweala also wants to know which countries or sectors would be adversely affected by the proposal and any ideas you may have for overcoming their concerns. Draft a memo of no more than 1500 words responsive to her concerns and offering your opinion about the merits of the proposal.

End of exam