Potential Legal Barriers to Getting a Covid-19 Vaccine or Treatment to New Zealanders

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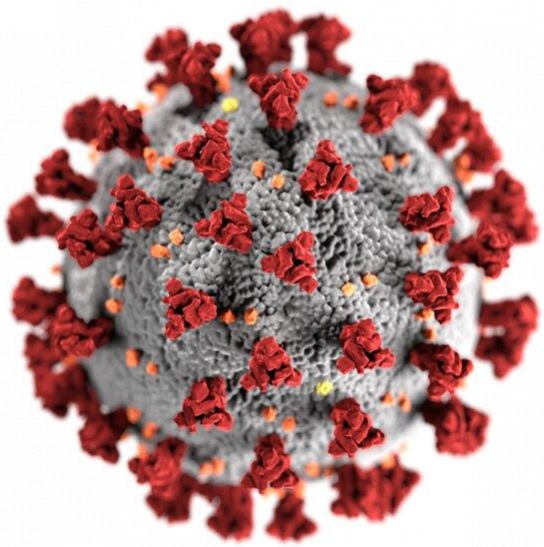


- Patent law
- Regulatory review of medicines

- International context
- National context

Some International Context

WORLD TRADE ORGANIZATION

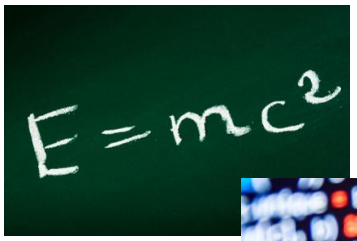
- Agreement on Trade-related Aspects of Intellectual Property Rights ("TRIPS")
- NZ has a dualistic legal system.
- Patents are territorial.

Patents Act 2013

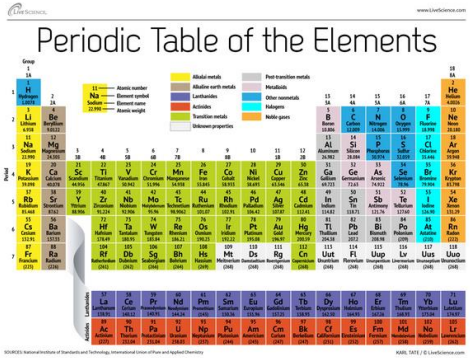
- Novel; and
- Involves an inventive step; and
- Is useful.

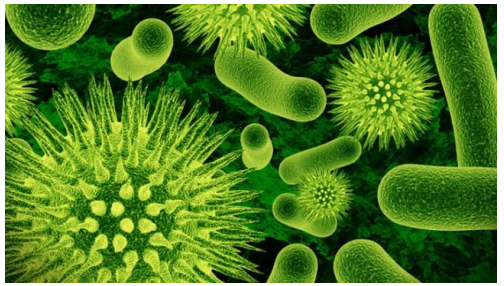
And is a “manner of manufacture”

Not patentable: mathematical algorithm or “natural law”



Not patentable: discoveries

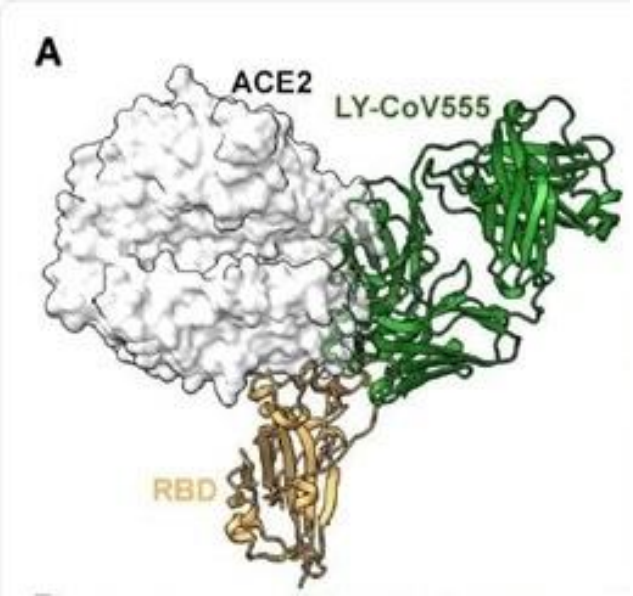




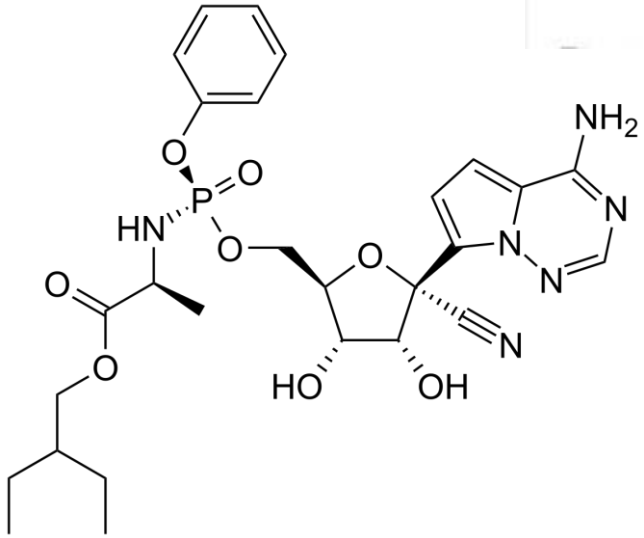
New species/variety

Can Patent:

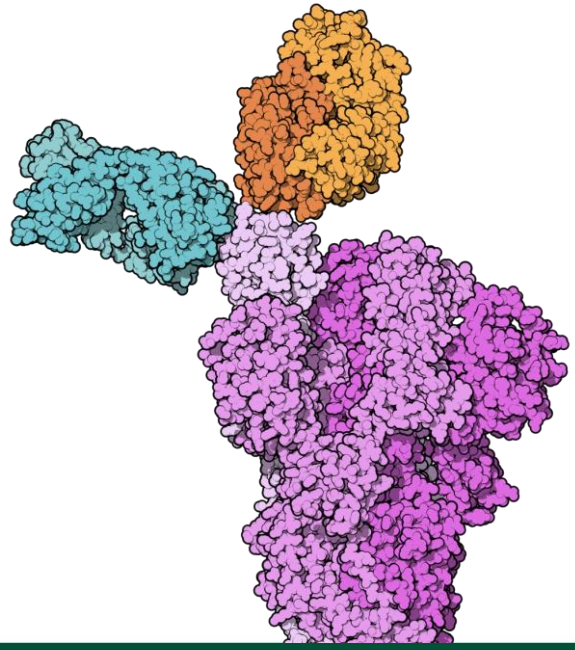
- The mechanical, chemicals
- Uses of natural species
- Isolated chemicals or genes



Bamlanivimab



Remdesivir



Regeneron

WORLD / COVID-19

Covid-19: Pfizer says virus vaccine 90% effective

10:58 am today

Pfizer says its experimental Covid-19 vaccine is more than 90 per cent effective, a major victory in the fight against a pandemic that has killed more than a million people.

WORLD / COVID-19

Moderna Covid-19 vaccine shows nearly 95% protection, company says

6:01 am today

By **James Gallagher**, BBC Health and science correspondent

A new vaccine that protects against Covid-19 is almost 95 percent effective, early data from US company Moderna shows.

12 OCTOBER 2020

First COVID-19 vaccine purchase agreement signed

Hon Dr Megan Woods | Hon Chris Hipkins

Health | Research, Science and Innovation

The Government has signed an agreement to purchase 1.5 million COVID-19 vaccines – enough for 750,000 people – from Pfizer and BioNTech, subject to the vaccine successfully completing all clinical trials and passing regulatory approvals in New Zealand, say Research, Science and Innovation Minister Megan Woods and Health Minister Chris Hipkins.

"Our first vaccine purchase agreement has been signed and it brings to fruition some of the critical work going on behind the scenes to keep New Zealanders safe from COVID-19," says Megan Woods.

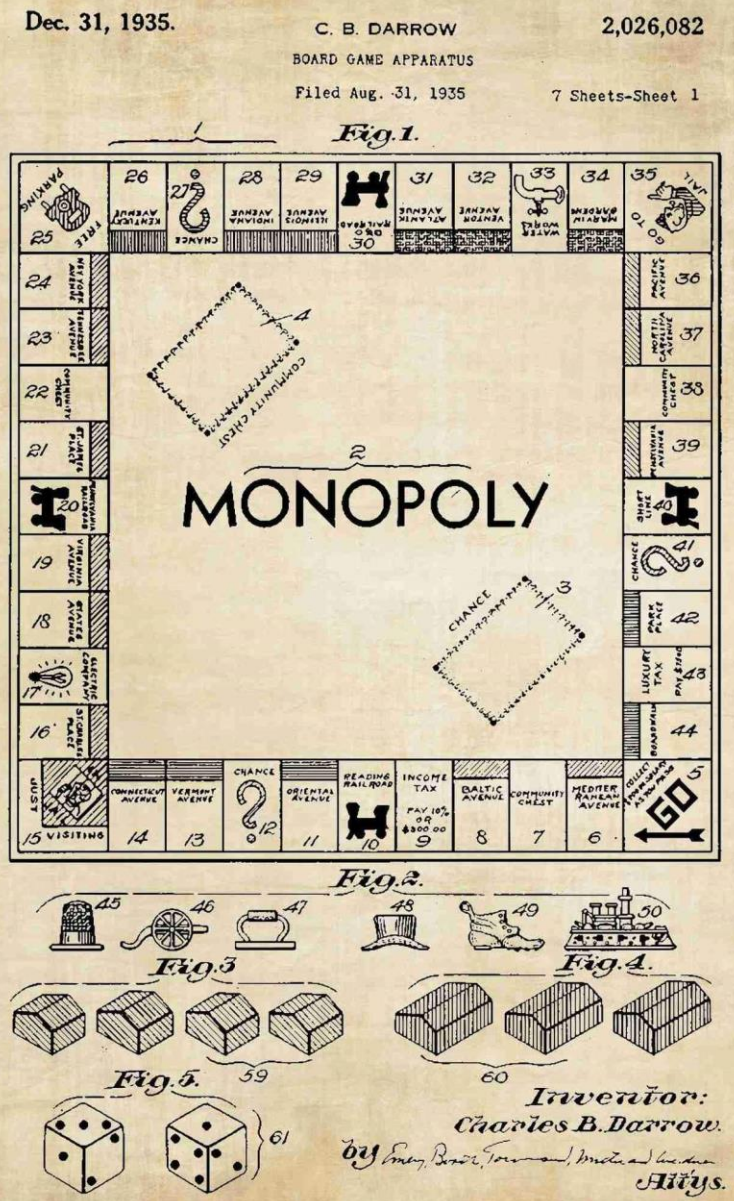
"As part of the agreement, vaccine delivery to New Zealand could be as early as the first quarter of 2021. This is just the first tranche of work in a multi-pronged approach to ensuring we secure vaccines for New Zealanders.

Megan Woods says "Pfizer have said they are making good progress with the development of a COVID-19 vaccine. Subject to clinical and regulatory success, and provided the vaccine is approved for use here in New Zealand by Medsafe, it is possible that some doses will be available to us in the first part of 2021."

The agreement with Pfizer is complementary to other aspects of the Government's COVID-19 Vaccine Strategy, such as the global COVAX Facility that could provide up to 50 percent of our population's needs.

"A key aim of our portfolio approach is to ensure we have flexibility and choice when it comes to securing the right vaccines for New Zealand and our Pacific neighbours."

Megan Woods said the COVID-19 Vaccine Strategy Task Force is currently negotiating with other pharmaceutical companies, and further announcements are expected in November. "The agreement with Pfizer and BioNTech is the first of a number of negotiations underway as part of our portfolio approach, and good progress is being made in relation to other purchasing negotiations. The additional agreements will ensure that once the portfolio is completed, we will have sufficient COVID-19 vaccines for the whole population," said Megan Woods.



Dec. 31, 1935. C. B. DARROW 2,026,082

BOARD GAME APPARATUS

Filed Aug. 31, 1935 7 Sheets-Sheet 1

Fig. 1.

MONOPOLY

COMMUNITY CHEST

CHANCE

Fig. 2.

Fig. 3

Fig. 4.

Fig. 5.

Inventor:
Charles B. Darrow.
by Emery, Booth, Townsend, Miller and Emery
Attys.

IF THERE ARE VALID PATENTS AND THE PATENTEES DEMAND EXORBITANT PRICES?

(a) Compulsory Licensing

s 169 Application for compulsory licence where market is not being supplied, or is not being supplied on reasonable terms, in New Zealand

s 176 Person applying for licence must have made efforts to obtain licence from patentee on reasonable commercial terms and conditions

Patent Rights and Wrongs in the COVID-19 Pandemic: EU and U.S. Approaches to Compulsory Licensing

By Nafsika Karavida & Dara Onofrio & Deena Merlen
May 19, 2020

Print Article 6

"There are ways to ensure access to life-saving medicines, including a future COVID-19 vaccine. However, the European Union and the United States, which constitute the largest economies in the world, have diverging views on compulsory licensing."

As governments around the globe fight the COVID-19 outbreak, pharmaceutical companies race to develop a vaccine and potentially secure a patent for it. To speed the process, much of that effort builds on known drugs for other diseases. The World Economic Forum reports that 70 potential vaccines are currently in development around the world. According to a BBC report, research is in progress on more than 150 additional

TRIPS Agreement, Article 31

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. …;

Recommendation: amend legislation so that in a national emergency, anyone can apply for a compulsory licence at any point, without the requirement to negotiate with the patent owner first.

(b) Crown Use

s 179 Crown use of inventions

(1) Any government department, and any person authorised in writing by a government department, may exploit any invention for the services of the Crown at any time after the complete specification relating to an application for a patent for the invention has become open to public inspection.

s 186 Nature and scope of rights under section 179

(3) The right to use an invention under section 179 is, except in a case to which section 185 applies, subject to the government department or person authorised by a government department under section 179 having first made efforts to obtain the consent of the nominated person or the patentee for the use of the invention on reasonable commercial terms and conditions, and having failed to obtain that consent, or to obtain that consent on reasonable commercial terms and conditions, within a reasonable period of time.

s 185 Special provisions as to Crown use during emergency

(1) The powers exercisable in relation to an invention by a government department or a person authorised by a government department under section 179 include the power to exploit the invention for any purpose that appears to the government department necessary or desirable—

(a) to avoid prejudice to the security or defence of New Zealand; or

(b) to assist in the exercise of powers and the implementation of civil defence emergency management during a state of emergency declared under the Civil Defence Emergency Management Act 2002.

Beehive.govt.nz
The official website of the New Zealand Government

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25 MARCH 2020

State of National Emergency declared to fight COVID-19

Rt Hon Jacinda Ardern

Prime Minister

A State of National Emergency has been declared across the country as the Government pulls out all the stops to curtail the spread of COVID-19.

"Today we put in place our country's second ever State of National Emergency as we fight a global pandemic, save New Zealanders' lives and prevent the very worst that we've seen around the world from happening here," Prime Minister Jacinda Ardern said.

Recommendation: amend definition of "emergency" to specifically include health emergencies.

Biocell

27 August 2020 Beehive Press Release, Rt Hon Jacinda Ardern, Rt Hon Winston Peters and Hon Dr Megan Woods

“We are also investing in local manufacturing, which may provide us with the ability to contribute to global supply. Biocell will receive $3 million to upgrade existing facilities so that it has the necessary scale to support global vaccine supply. This also provides the potential for New Zealand to manufacture COVID-19 vaccines locally.”

Our Obligations in the Pacific?

Compulsory Licensing, s 171 Court may order grant of licence for export of pharmaceutical products to certain countries

If "(b) the pharmaceutical product is needed to address a serious public health problem in 1 or more overseas countries specified in the application (for example, an epidemic, whether actual or imminent, of HIV/AIDS, tuberculosis, malaria, or other disease);"

Crown Use, s 179(4)

For the purposes of this subpart,—

(b) the power of a government department or a person authorised by a government department under this section to exploit an invention includes the power to sell to any person any products made in the exercise of the powers conferred by this section that are no longer required for the purpose for which they were made:

Regulatory Review of Medicines

Medicines Act 1981, s 21(2)

(c) details of the method of manufacture of the medicine:

(d) a full statement of the ingredients named by the descriptive or non-proprietary names of the medicine, including details of the quantities in which they are present:

(e) a description of the quality of the raw materials used in the manufacture of the medicine:

(f) a description of the form or forms of the medicine:

(g) the proposed or recommended dosage and frequency of dose, and the manner in which the medicine will be recommended to be administered, applied, or otherwise used:

(h) the purposes for which the medicine will be recommended to be used, and the claims or representations to be made in respect of its usefulness:

(i) reports of any tests made to establish the safety of the medicine for the purposes for which and in the manner in which it is intended to be used:

(j) reports of any tests made to control the strength, quality, purity, or safety of the medicine and of the method of testing:

(k) any reports relating to the efficacy of the medicine:

s 22 Procedure in respect of applications for Minister's consent

(1) On receipt of an application for his consent to the distribution of a medicine for the purposes of section 20(2), the Minister shall—

(a) consider all the particulars and information relating to the medicine submitted under section 21, and such other matters as appear to him to be relevant; and

(b) as far as practicable, weigh the likely therapeutic value of the medicine against the risk (if any) of the use of the medicine injuriously affecting the health of any person.

- ss 24C-24G Approval of medicines required for use in special emergency: "in a special emergency a medicine that is or contains a hazardous substance or new organism"

- **Recommendation**: Introducing a narrow regulatory approval highway.

Generics?

Originator applies for regulatory approval.
- Submits data on efficacy and safety etc.

5 years of data exclusivity

Generic entity wishes to enter market
- Submits data showing their product is equivalent to the originators.
- Asks Medsafe to use Originator's data on efficacy and safety etc.

s 23C(1). Notwithstanding section 23B, the Minister may, during the protected period in relation to confidential supporting information,—

(a) disclose that confidential supporting information, or use that confidential supporting information for the purposes of determining whether to grant any application other than the application to which it relates or related, as the case may be,—

(ii) if that disclosure or use is, in the opinion of the Minister, necessary to protect the health or safety of members of the public