

## Episode: Ethics Talk – Equity and Intellectual Property Protection of COVID Vaccines

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[bright theme music]

TIM HOFF: Welcome to *Ethics Talk*, the *American Medical Association Journal of Ethics* podcast on ethics in health and health care. I'm your host, Tim Hoff. This episode is an audio version of a video interview conducted by the journal's Editor in Chief, Dr Audiey Kao, with Professor Ana Santos Rutschman, an Assistant Professor of Law at the St. Louis University School of Law, about the impact of intellectual property regimes on domestic and global responses to the COVID-19 pandemic. To watch the full video interview, head to our site, [JournalOfEthics.org](http://JournalOfEthics.org), or check out our [YouTube channel](#).

DR AUDIEY KAO: Professor Rutschman, thanks for being a guest on *Ethics Talk* today.  
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DR ANA RUTSCHMAN: Thank you for having me.

KAO: So, what do you see as the role of intellectual property protections in spurring research and development of vaccines, which many see as a public health good?

RUTSCHMAN: Mhmm. It is a great question. And I'd like to just start by talking about intellectual property as a concept, because different people mean different things when they talk about intellectual property. And I think in some of the debates that we've been having in the pandemic, keeping the different functions and things that intellectual property does and does not do sometimes gets a little mixed up. And our responses to things that we think are wrong with intellectual property, with innovation regimes, might depend on exactly which part of intellectual property we're talking about. You talked about IP as an incentives regime, right? We do something that the law normally would not do. We are going to restrict competition on goods that will range from widgets to public health goods, which is how I would define vaccines. Law tends not to allow this to happen in the first place, but now we encourage this because we think this is necessary as an incentive to do innovation.

In that sense, if you're thinking of IP as a set of incentives, I think it's a really poor fit for goods like vaccines. Vaccines are not the only types of goods that pose problems when we try to commodify them like this and say this is going to be a market-dependent model, and the first to market gets—for almost up to 20 years in practice—to be the only one, okay, who competes in this area. So, that's part of the problem we have, right? And it's not a COVID-specific problem. It's a problem that derives from the fact that pretty much, this is how the majority of vaccines we produce at this point are subject to this model, which is a market-based model. Public health never fares very, very well when you have a lot of predominantly private sector actors operating this way. So, we're not faring particularly well there. We have not been faring, I think, particularly well there for decades now.

That being said, is intellectual property the major hurdle in the COVID-19 pandemic? I think it informs a lot of what's happening, but ultimately, the real barrier is more on the contracts side of things. The people who get to negotiate these contracts, the companies and the governments involved, obviously, they play the game the way they do because there's an IP-informed background. But IP should not stand in the way of the allocation of vaccines, of lessening competition standards that are our ethos during the pandemic. That's not IP necessarily at work, IP as contributed to the framework. But this is how we pretty much subject vaccine production and distribution to standard contracts. That's where we stand, and I think that's where most of the trouble is coming.

KAO: So, given what you just said, publicly funded research into messenger RNA was critical in the development of currently available COVID-19 vaccines. So, how should intellectual property inform contracts be structured to avoid socializing costs and privatizing benefits of vaccines?

RUTSCHMAN: Mmhmm. So, I think that the problem here is that current practices are different from IP, as I see it in the books, right, the black letter of the law. We can disagree with the principle that some goods should be subject to incentive regimes that are structured around IP. That's one thing. But once we've collectively decided to make that decision, say this is the regime in place, there were several safeguards that were built into the law and said in some circumstances, we're going to limit the reach of proprietary rights. And I think that, in theory, we have that framework in place, and that should speak to things like public funding having gone into the development of critical components of some of these vaccines. Whenever you have public funding accounting for a lot of what is happening at the development level, the law does a number of different things, and these are not the only IP protections, but the ones that are relevant in the case of publicly funded inventions. It says that the funding agencies have certain rights when it comes to using or deciding what can be done with the invention, which in this case is going to be a particular type of a vaccine.

In the case of Moderna, for instance, it seems that in addition to public funding for the R&D, we're also talking about such degree of involvement of work on part of public sector scientists that the question of co-ownership of the vaccine also came into play. So, you might have a situation of co-ownership, and then, it's pretty much like when you own something like a house and there is more than one person. And it's not that everybody has only 50 percent of the house. You get control in that house. You have to bargain, but you control the entirety of it. So, the law has accounted for situations of co-ownership in which one of the parties, one of the co-owners, can be the government. And then the government has broad leeway to do a number of things that our governments have typically not done: set pricing ceilings, authorize manufacturing by others that would increase the amount of vaccine available to everybody. This is not as easy to do as it might sound, but it's a possibility that the law contemplates.

And in the case of transfers of technology from the public sector to the private sector, the funding agency retains what we call march-in rights, meaning that if there's a public health crisis, that agency should have the ability, in order to satisfy the public interest to say, well, we're going to allow somebody else to step in and manufacture this product. As I said, this exists in the legal framework. So, IP theory is, I think, working. What's not working is IP practice. And unfortunately, it's not just during COVID. We've never, ever had a march-in right that was successful in the history of the U.S. And we've talked about oncology drugs. Now we're talking about potentially vaccines. We've talked about administrations leaning more to the right, more to the left, you name it. We've never had a

successful march-in right. So, the protections exist in theory. In practice, however, things are very, very different.

KAO: So, given what you just said about the distinction between theory and practice, one of the things the federal government did was, through Operation Warp Speed, expedited production and availability of COVID-19 investigational vaccines by having the U.S. federal government finance much of the manufacturing ramp-up costs before the vaccines were authorized for emergency use by the FDA. What intellectual property considerations have or should have been incorporated in this public/private partnership?

RUTSCHMAN: So, this idea that the government plays a fundamental role in helping even the private sector bring products to market makes a lot of sense, particularly now, right? In the mid-20th century, you would have a lot of basic R&D, and you still do to some extent, but occurring in the public sector. But funding for that has decreased. So, these collaborations are crucial. That being said, that does not mean that we should necessarily think that because we are much more dependent now on the private sector than we were back in the day, they had contracts. And that this is why I really think this is all about licensure and contracts, really, and how poor a fit current licensing and contractual frameworks are IP and beyond IP. It doesn't mean that things need to be necessary tilting towards the protection of the interests or the exclusive rights of just one of the players, which would be, in this case, the companies that do manufacture these vaccines. And I cannot understate, I don't want to understate, the role that they play. Without them we would not have the vaccine doses that we have today, insufficient as they are for the tremendous public health needs.

That being said, that does not mean that the contracts should not contemplate things like allocation of vaccines, patented or potentially patented vaccines. Just because they are patented, that does not mean that we cannot contractually agree to certain patterns of allocation. It does not mean that we cannot ex-ante before the need actually arises, account for things like the need to have other companies that normally you would not cooperate with as an individual, highly-competitive private sector company, but just account for the fact that we are facing, we're likely to face—and we knew that—massive scarcity. So, all of this can and should be incorporated into these contracts. Part of them are licensure contracts, and this is patent technology. This is how we're going to transfer it.

Some of these other concerns are not directly related to patents but have to do with affordability of vaccines. When do you start sending doses to populations sorely need outside the West, the contracts typically don't talk about this, don't talk about affordability of vaccines. We don't have a problem now, but we could, right?

KAO: Sure.

RUTSCHMAN: The position of the administration was that we cannot control the prices of vaccines, which is not accurate from the, legally, from the perspective of the ability. You can. You choose not to for certain reasons, but you can. Contracts still do not cover these kinds of scenarios, and that's what I see as very problematic. Just because something is patented, it is never meant, no court has ever said that control was absolute, pretty much as control of your house is not absolute. And we impose a number of restrictions on you that range from sometimes letting you, letting certain companies walk over your property. And sometimes we take the pay, but we take your property away from you. And intellectual property in that regard works the same, except in practice, it tends not to.

KAO: So, given what you just said, vaccine nationalism has been used to describe countries, usually in the global North, securing vaccines for their own populations at detriment to countries in the global South. What should we appreciate about how patent protections and IP exacerbating longstanding global health inequity?

RUTSCHMAN: Mhmm. I think they are a contributing factor, indirectly. Because what intellectual property's about is saying you get property-like rights over a particular good, and we apply that across the board, making no distinction there. There are very few things we say, oh, you cannot patent yet. Conceptually, there's very few things that we say, "This is excluded." So, most health innovations that we're familiar with and we'll need throughout the pandemic, from PPE equipment to respirator valves to vaccines, treatments, you name it, all of it is potentially patentable. What IP does is to say, for up to 20 years, nominally 20 years, this owner—this company, this person, this institution—is going to be the only one controlling any aspects related to this technology, absent some intervention like the ones we've discussed: The state, the government, the agency decides to do something. So, if this is the default, IP is giving these entities, this very limited number of players, enormous power over anything that's done with the protected technology, including who you're going to sell it to or provide it to.

And what we're seeing is that this aspect of IP, which we've always known about this is how the system was structured, we know that this needs to be coupled with other considerations, particularly when we stop talking about shares or still and you talk about health goods. And things get even more critical when we get to the type of health good that we're discussing today, which really is something that's needed to respond to a global public health problem. So, what IP is indirectly enabling us to do is to have then contracts on distribution preorders because that's how vaccine nationalism has been operationalized. What IP has enabled is a scenario in which whoever controls the IP can either start a contractual relationship or agree to one in which we say, "And these vaccines go to U.S. citizens or whoever is living in the United States."

So, what is missing is, either within IP but also within international law, contractual frameworks, a mechanism that says, hold on. There are particular types of goods that it doesn't make sense if we just allocate them based on jurisdictions, right? Because IP controls what happens in the U.S., but we're essentially saying, and now the contracts that U.S., the IP you get to, to get into, you also get to provide just the goods for this market. So, this is what's missing. There's no legal provision, there's no treaty, there's no law or case that I'm aware of that would say, hold on a moment. It's a global public health problem. We need a more centralized solution. You can engage into those, but that's all voluntary. And a lot of the companies and governments have not been participating in this.

KAO: So, given that, to promote global health equity, what do you see as the most compelling changes to intellectual property law that would promote better international collaboration in vaccine development and distribution?

RUTSCHMAN: So, I think there's a couple of things that we do on a smaller scale already that we should definitely do on a much, much bigger scale because nationalism is not new. This happened in the previous pandemic and with swine flu in 2009. It happened throughout the 20th century in different forms, just with vaccines. So, we know this is bound to happen again. The immediate answer that we saw during COVID, which I think is, it's definitely a step in the right direction, but just not enough, was the formation of COVAX, which pretty much functions as a procurement institution, pretty much like Gavi already does for childhood vaccines, and pretty much flips the scheme on its head by

saying, oh, these pre-purchase or pre-production agreements that we have, we are just going to use those and then put some strings, attach some strings when it comes to allocation and try to start allocating vaccines on a more global level. This is a very small effort. Again, incredibly important, but obviously, during a pandemic, you can't ramp up such a collaborative scale like this.

So, I think that what we can do on the IP side of things is to not redesign the system. I would love to have a system that's redesigned, but if I were to say, you know, vaccines need to be treated in particular ways, it will subtract the amount of IP protection we give to them. Much as I would like to have this, there's an international treaty called TRIPS, and Article 27 is going to say you cannot treat different types of technology differently; they all get the same type of patent protection. So, ideally, I would like to actually tinker with something along those lines, but this is going to realistically need a lot of international agreement on a very divisive topic.

So, here's what we can do. We can say, okay, we know that some countries—and at this point with the U.S. back into international cooperation frameworks—we know that a majority, a large majority, of countries does like something like COVAX. It's underfunded, right? It's smaller than we would like it to be. But we know the next pandemic is coming. We even have from the WHO lists of potential pathogens that are likely to cause, viral families, and they are likely to cause upcoming pandemics. We can do things like patent pools, we can do things like patents pledges, and we can have COVAX-like structures in place. What I mean by this is to say we can have companies, institutions, governments pledging certain types of technology that everybody will be able to use, you know, after they pay a fee, should there be another pandemic. So, the moment the next pandemic or large public health crisis is declared, we can have just a pool of technology ready to go, and there's no back and forth: Can I do this? Will you allow me to use your technology? How much do I need to buy? We can solve those questions, those bargaining questions in advance. And it's up to the patent owners to pool or to pledge their technology.

This also happened during COVID. A couple of law professors, Professor Lemley and Contreras, actually worked on, with a few other lawyers, on a pledge for COVID-19 technology. It's a really great initiative. I would like to see more vaccine technology going into that pool. And I think after this pandemic starts, hopefully soon, to come to an end, this would be the right time for us to start populating a pledge to start creating a pool of technology that you just know how much you're going to pay and license the technology you need to produce the next vaccine, but also treatments and other things. So, I think we can do this with an IP. We can scale up COVAX, make it permanent, because it's not, right? It's a remedial structure. And these would be modest steps, and we would be marginally better. And we would have less nationalistic approaches come the next pandemic.

KAO: Yeah. Well, on that note, I want to thank Professor Rutschman for sharing her insight and expertise with our audience today. Professor Rutschman, thanks again for being a guest on *Ethics Talk*.

RUTSCHMAN: Sure thing.

KAO: For more COVID ethics resources, please visit the *AMA Journal of Ethics* at [JournalOfEthics.org](https://www.journalofethics.org). Thank you for being with us today. We'll see you next time on *Ethics Talk*. [bright theme music plays]