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Drug Resistance, Patents and Justice: Who Owns the Effectiveness of Antibiotics?

James Wilson

Introduction

The wide availability of penicillin from 1945 onwards, and the subsequent rapid progress in discovering new antibiotics revolutionized medicine.¹ Salk's polio vaccine, and the success of the campaign to eradicate smallpox further contributed to a widespread optimism that infectious disease had been conquered.²

This has proved a vain hope. Communicable diseases still account for 15 million deaths per year. Communicable diseases still account for 13 million deaths per year. This is 25 per cent of the global burden of disease.³ The slow progress on the burden of communicable disease is due most obviously to a collective failure to secure the basic prerequisites of healthy life for more than a billion of the world's poorest people: clean water, access to improved sanitation, adequate nutrition, shelter, air quality and health facilities.⁴

1 For an accessible introduction to these changes, see James Le Fanu, *The Rise and Fall of Modern Medicine* (London: Little, Brown and Company, 1999).

2 A widely-quoted, but possibly apocryphal, statement by the US Surgeon General, William Stewart has come to emblemize this mood of optimism: 'The time has come to close the book on infectious diseases. We have basically wiped out infection in the United States.' This statement is said to have been made around 1970, though as Battin et al. relate, it is difficult to find an original source for it: see Margaret P. Battin, Leslie P. Francis, Jay A. Jacobson and Charles B. Smith, *The Patient as Victim and Vector: Ethics and Infectious Disease* (Oxford: Oxford University Press, 2008), 3.

3 Rafael Lozano, Mohsen Naghavi, Kyle Foreman et al. 'Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010', *The Lancet*, 2012, 380(9859): 2095–128.

4 See Yvonne Rydin, Ana Bleahu, Michael Davies, Julio D. Davila, Sharon Friel, Giovanni De Grandis, Nora Groce, Pedro Hallal, Ian Hamilton, Philippa Howden-Chapman, Ka Man Lai, C. J. Lim, Juliana Martins, David Osrin, Ian Ridley, Ian Scott, Myfanwy Taylor, Paul Wilkinson and James Wilson, 'Shaping Cities for Health: The Complexity of Planning Urban Environments in the 21st Century', *The Lancet*, 2012, 379(9831): 2079–108, available at <http://press.thelancet.com/healthycities.pdf>.

It is also becoming increasingly apparent that the microbes which cause communicable diseases provide an even sterner long-term challenge to earlier optimistic predictions. This is the challenge of drug resistance. The burden of disease from drug-resistant pathogens is already considerable, and is expected to continue to rise. Multi-drug-resistant tuberculosis alone now accounts over 15,000 deaths per year.⁵ Even in the European Union, multi-drug-resistant bacteria account for over 25,000 deaths per year.⁶

This chapter examines how we should think about intellectual property in antibiotics, given the fact of drug resistance. I argue that even when a company is granted a patent on the manufacture of antibiotics, the resource of antibiotic effectiveness that is depleted when those drugs are used remains the common property of humanity. As we shall see, this result has important implications for how antibiotics may legitimately be used, and who should profit from them.

The nature of antibiotic resistance

Antibiotics are drugs that aim to cure disease by interfering with some aspect of the life processes of pathogens such as microbes and viruses.⁷ In order to be useful as drugs, antibiotics need to be selective in their action: they need to be able to interfere with the life processes of pathogens, without interfering too much with the life processes of the human body. We can distinguish between narrow and wide spectrum antibiotics: narrow spectrum antibiotics are highly specific in the pathogens that they target, while wide spectrum antibiotics are effective against a broader range.

Pathogens are said to develop *antibiotic resistance* when specific antibiotics lose their ability to kill or inhibit the pathogen's growth. Given the variety of pathogens, antibiotics and possible dosing regimes, a more precise definition of antibiotic resistance would be 'the capability of a *particular* pathogen population to grow in the presence of a *given* antibiotic when the antibiotic is used according to a *specific* regimen'.⁸

5 World Health Organisation, *Fact Sheet 194: Antimicrobial Resistance* (Geneva: World Health Organisation, 2011), www.who.int/mediacentre/factsheets/fs194/en/.

6 European Medicines Agency and European Centre for Disease Prevention and Control, *Joint Technical Report: The Bacterial Challenge – Time to React*, 2009, http://ecdc.europa.eu/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf.

7 Karl Drlica and David S. Perlin, *Antibiotic Resistance: Understanding and Responding to an Emerging Crisis* (New Jersey: FT Press, 2011), 31. In non-technical usage, antibiotics are often treated as synonymous with antibacterials, as, for example, when it is argued that doctors should not prescribe antibiotics for a viral infection. As it is the phenomenon of resistance we are interested in here, and the problem of drug-resistant pathogens goes broader than drug-resistant bacteria, I use antibiotic in this broader sense in this chapter.

8 Drlica and Perlin, *Antibiotic Resistance*, 8.

Antibiotic resistance is ancient.⁹ Bacteria and other pathogens have existed as part of a Darwinian struggle for life for over three billion years. Those that have survived this far have already faced selection pressures in which the ability to resist naturally occurring antibiotics has increased reproductive fitness. For example, some bacteria have developed efflux pumps – and so can automatically pump antibiotics out of their cells before the antibiotics have a chance to kill them. Antibiotic resistance which predates the introduction of a given antibiotic is known as inherent resistance.

Other antibiotic resistance is acquired: this occurs when pathogens that were previously susceptible to antibiotics become resistant to them as a result of genetic mutations: for example, by modifications of the target site or metabolic pathway that the antibiotic had previously made use of. The greater the number of pathogen cells that come into contact with a given antibiotic, the greater the likelihood of mutations which confer antibiotic resistance developing. Although mutations which increase antibiotic resistance are rare, the number of pathogen cells exposed to antibiotics is so large that such mutations occur frequently.¹⁰

Antibiotic stewardship

There are three main strategies for controlling the spread of antibiotic resistance, which must be used together in a coordinated fashion. Given that antibiotics by their nature create selection pressures for new resistant strains, the first plank of responsible antibiotic stewardship is to limit the use of antibiotics. Antibiotic use can be limited in the first instance by ensuring (where time and resources allow) that antibiotics are appropriately targeted to pathogens. Ruling out prescribing antibacterials for viral infections and banning worldwide the addition of antibiotics to feed for healthy farm animals would greatly help.¹¹ Second, and more controversially, even where the specific pathogen is

9 Vanessa D'Costa, Christine King, Lindsay Kalan, Mariya Morar, Wilson Sung, Carsten Schwartz, Duance Froese, Grant Zazula, et al., 'Antibiotic Resistance Is Ancient', *Nature*, 2011, 477 (7365): 457–61.

10 Drlica and Perlman relate that the number of antibiotic prescriptions in the United States is 100 million per year, and that the number of pathogen cells in an infection is usually over 1 million. This would imply that somewhere in the region of 10^{14} pathogen cells are subjected to antibiotics per year in the United States alone (*Antibiotic Resistance*, 76)

11 Over 50 percent of the antibiotics used in the United States are used in agriculture. See M. Lipsitch, R. S. Singer, B. R. Levin, 'Antibiotics in Agriculture: When Is It Time to Close the Barn Door?', *Proc Natl Acad Sci USA*, 2002, 99: 5752–4. Examples of increased antibiotic resistance in humans from agriculture include the rise of quinolone-resistant enteritis after the introduction of fluoroquinolones in poultry feed. See K. E. Smith, J. M. Besser, C. W. Hedberg, F. T. Leano, J. B. Bender, J. H. Wicklund, B. P. Johnson, K. A. Moore and M. T. Osterholm, 'Quinolone-Resistant *Campylobacter* Jejuni Infections in Minnesota, 1992–1998', *The New England Journal of Medicine*, 1999, 340 (20):1525.

susceptible we can appeal to the opportunity cost of prescribing antibiotics for relatively trivial ailments.¹² Any proposed use must be of sufficiently high value that it is worth the opportunity cost of later persons suffering a greater risk that their treatment will be ineffective.¹³

The second plank is to ensure that where antibiotics *are* used, they are used in a way that will minimize the risk of resistant strains developing and spreading. The best treatment regimen to do this will vary from pathogen to pathogen, depending among other factors on the number mutations that are necessary for a wild-type strain to undergo before it gains resistance to a given antibiotic, the frequency of such mutations, and what costs these mutations place on reproductive fitness.¹⁴ The emerging picture of research is that appropriate regimens can help us to eke out the effectiveness of antibiotics, but cannot prevent its inexorable rise.¹⁵

The third plank is to ensure that new antibiotics are discovered and brought onto the market, to replace those that are becoming ineffective. Currently new antibiotics are being brought to market much more slowly than already existing antibiotics are losing their effectiveness.¹⁶

12 K. R. Foster and H. Grundmann, 'Do We Need to Put Society First? The Potential for Tragedy in Antimicrobial Resistance', *PLoS Med*, 2006, 3: e29.

13 I discuss inter temporal opportunity costs and healthcare resource allocation in James Wilson, 'Paying for Patented Drugs is Hard to Justify: An Argument about Time Discounting and Medical Need', *Journal of Applied Philosophy*, 2012, 29(3): 186–99.

14 It has often been assumed that the best model is aggressive drug treatment which is continued until the end of the prescribed course, even if the patient feels better much before this. However, recent work on mathematical models of drug resistance has shown that there can be cases (e.g. in malaria treatment) where aggressive treatment may be less effective at limiting drug resistance. See Andrew F. Read, Troy Day and Silvie Huijben, 'The Evolution of Drug Resistance and the Curious Orthodoxy of Aggressive Chemotherapy', *Proceedings of the National Academy of Sciences*, 2011, forthcoming, doi:10.1073/pnas.110029910. See also L. B. Rice, 'The Maxwell Finland Lecture: For the Duration – Rational Antibiotic Administration in an Era of Antimicrobial Resistance and *Clostridium Difficile*', *Clinical Infectious Diseases*, 2008, 46(4): 491–6.

15 It was initially thought that the effectiveness of antibiotics could be maintained by employing them in scientifically determined rotation. The assumption was that maintaining resistance to a particular antibiotic would have some cost in fitness to the bacterium in an environment where this antibiotic was not present, and so we should expect drug-resistant strains to die out if we allowed particular antibiotics to lie fallow for a period of time. However, evidence of the effectiveness of antibiotic cycling is weak, and in addition there are a number of theoretical reasons for thinking that it could at best somewhat retard, but not stop, the growth of antibiotic resistance. For a review of the empirical evidence, see E. M. Brown and D. Nathanwi, 'Antibiotic Cycling or Rotation: A Systematic Review of the Evidence of Efficacy', *Journal of Antimicrobial Chemotherapy*, 2005, 55: 6–9. At a more theoretical level, the problem is that there need only be a very small number of resistant bacteria in the environment for resistance to be a problem: as soon as the antibiotic that has been lying fallow is brought back, we then select in favour of the resistant bacteria, and soon see a sharp rise in their numbers. Second, the assumption that resistance to antibiotics inevitably has a high cost for the bacterium is not true: bacteria can and do mutate in such a way as to reduce the survival cost of antibiotic resistance.

16 Cantal M. Morel and Elias Mossialos, 'Stoking the Antibiotic Pipeline', *BMJ*, 2010, 340, bmj.c2115.

Each of these three strategies only underscores the starting point of my argument, which is that the effectiveness of each particular antibiotic is a limited resource. The correct analogy for any particular antibiotic is not something like the stocks of a particular fish which can be prudently managed so that they replenish themselves over time, but rather a limited resource like oil or coal. We can steward antibiotics more or less responsibly, but whenever we use any particular antibiotic we contribute to the conditions in which it becomes ineffective.

Three levels of ownership in antibiotics

We can distinguish between three different levels at which the resources required to deliver effective antimicrobial treatments can be owned. Our interest is in the relationship between the second and the third.

- 1 *Ownership of physical stocks of antibiotics.* Stocks of antibiotics are physical goods. Ownership of physical stocks of antibiotics raises ethical issues where there is either a scarcity in the supply of the tablets in question, or if people who need access to the tablets to prevent them suffering serious harm are denied access to the tablets.
- 2 *Ownership of the intellectual property on a particular antibiotic compound.* Patents grant ownership and control rights over *types* of objects rather than concrete particulars.¹⁷ Rights are granted over the use of an antibiotic compound for a particular purpose. An antibiotic patent does not give ownership over physical stocks of the compound, but it does give the monopoly right to control the manufacture and use of the compound for the period of the patent claim.
- 3 *Ownership of the effectiveness of each particular antibiotic.* We have seen that the effectiveness of each particular antibiotic is a limited resource. We cannot distribute and use antibiotics without depleting this resource.

The key question concerns the relationship between the second and the third types of ownership: does ownership of a patent for a given antibiotic bring with it the private ownership of the underlying resource of antibiotic effectiveness during the period of the patent? Or should we think of antibiotic effectiveness as an unowned resource that can be fairly appropriated by anyone? Or should we think of antibiotic effectiveness as a resource that belongs to humanity in common?

17 I write about the ethical implications of this fact at much greater length in James Wilson, 'Ontology and the Regulation of Intellectual Property', *The Monist*, 2010, 93(3): 453–66.

Patents do not usually give the patent holder a temporary monopoly on extracting the value from a limited resource that has significant implications for human well-being, and so the question of the relationship between the second and the third types of ownership has so far gone unexamined. Compare granting a patent on a new type of vacuum cleaner to a patent on a new antibiotic. When authorities grant a patent on a new type of vacuum cleaner it is not the case that each time one of these vacuum cleaners is used, it increases the likelihood of the development of mutant Hoover-resistant superdust. Nor is it the case that the decision to use vacuum cleaners for relatively trivial things like cleaning out the inside of a car will prevent people in the future from being able to them for more lofty purposes like capturing dust from inside their houses.

Inventions are by nature public goods: that is, they are non-rival and non-excludable. Standard economic theory tells us that unless we do something to incentivize their production we should expect an underproduction of public goods. It will tend to be irrational (in self-interested terms) to expend your own time and money creating a public good, given that everyone else will be able to benefit from the public good as much as you will. It is easier to allow someone else to do the hard work, and then take a free ride on their efforts. But of course, it will tend to be irrational (in self-interested terms) for anyone else to put the effort in either; and so there is a severe risk of under-creation of such goods. Even where such goods are produced, it will usually be rational (in self-interested terms) for the inventor to try to keep the underlying processes and ideas secret, so that she can reap an advantage for her work.¹⁸

The patent system is usually justified on the grounds that it provides the best solution to this public goods problem. Patents aim to solve the problem of under-provision by making patented inventions *excludable* and *public*. Provision to exclude others from the good is hypothesized to act as an incentive to do the necessary research and development to create useful new inventions: it will become rational to put the necessary effort in if you know that you will be able to recoup your costs (and return a profit) by charging others for access to the good. Patents attempt to solve the problem of secrecy by requiring that patentors disclose the basis of the patented item in such a way that anyone skilled in the art would be able to reconstruct it from the description. In order to gain a patent, the patent holder has to share the underlying knowledge of how the process or product can be made with everyone.

Thus, patent legislation is usually thought to have its justification in a quid pro quo; the inventor receives a temporary monopoly in order that the space of

18 In the past there have been some quite significant cases of the withholding of medical information. Most famously, the Chamberlen family kept the discovery of the obstetrics forceps secret for more than 100 years, in order to protect their midwifery business. (See Wendy Moore, 'Keeping Mum', *BMJ*, 2007, 334(7595): 698).

ideas which are available to all for effective use is expanded once the monopoly expires.¹⁹ Patents on antibiotics are difficult to reconcile with this model. While formulae for making antibiotics are public goods – and hence we will be able to make any amount of antibiotic tablets with a particular formula – the effectiveness of antibiotics is not. The knowledge about how to make an antibiotic that is brought into the public domain by the corresponding patent will typically be much reduced in usefulness, once resistant pathogens develop.

So a better mental model for thinking about the way current patents on antibiotics work would be granting a company an exclusive right to exploit a particular oil reserve for a limited period of time, with the stipulation that after the exclusive license period, anyone is permitted to exploit the oil in the reserve. In providing such a licence, we would be allowing the company the exclusive license to extract as much oil as they are able to from the oilfield during this period. We would usually think that this would be a rather unwise way of proceeding if our interest was in maximizing public benefit from the oil once the company's monopoly had expired.

Who owns the effectiveness of antibiotics?

The central moral question that this raises is who owns these resources of antibiotic effectiveness in the first place. There seem to be three basic answers:

- 1 *Finders Keepers*. On this view, the resource of the effectiveness of a particular antibiotic is owned by whoever discovers it: he or she has created something which did not previously exist (or used their art to refine something which previously did). The inventor has put the effort to turn a (potentially) naturally existing substance into a *drug* with the right pharmacodynamic and pharmacokinetic properties to be a saleable commodity. On this view, the inventor has a property right over this resource; he is within his rights to use up this resource in any way he sees fit, and no one else is able to make use of the resource without his permission.
- 2 *First come, first served*. On this view, the resource of the effectiveness of a particular antibiotic is initially unowned. Everyone has a liberty right

19 The US Constitution explicitly posits this link: the stated purpose of the copyright and patent statutes is to 'promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries'. (Article I, Section 8, Clause 8) On this general point, and what it should mean for the future of intellectual property regulation, see for example James Boyle, *The Public Domain: Enclosing the Commons of the Mind* (New Haven: Yale University Press, 2008).

to use this resource in whatever way he or she sees fit: the inventor is permitted to use the resource up, but so is everyone else.

- 3 *Common ownership.* On this view, the antimicrobial resources are commonly owned by humanity as a whole. There are certain duties of stewardship that make it wrong to use up resources which are held in common.

Let us start by considering a resource allocation case that is familiar from the literature. We can call this *Ordinary Pill Shortage*.

Ordinary Pill Shortage

There is a new deadly disease in our country. The only treatment that is effective against it is a new pill, and there are only 100 of these pills. Each one will be effective in curing the disease for one person. Once these pills are gone, we will not be able to get any more.

In resource allocation cases of this kind, it is standard to begin with two questions. First, who has a claim to be considered for the allocation of these pills? Second, among those who should be considered, how do we decide who should be of higher priority and who of lower priority? Compare this to a second case, which we can call *Super-resistant bacteria*.

Super-resistant Bacteria

There is a new deadly disease wreaking havoc. Knowledge of how to make a pill that will cure the disease is in the public domain, and there are a number of different factories in the world that could cheaply make large numbers of these pills. However, due to the super-resistance of the bacteria, after the hundredth person has taken their pill, the pills will no longer be effective against the disease.

How should we decide who should be allowed to take the 100 pills in this case? One important difference between the cases is that ownership of physical stock of pills plausibly matters in *Ordinary Pill Shortage*, whereas it is of much less relevance in *Super-resistant Bacteria*. In *Super-resistant Bacteria*, lots of different actors have the ability to make more than 100 pills. While ownership of 100 pills gives any actor the *power* to decide how the limited resource of this antibiotic's effectiveness will be used up, the fact that many others also have the same power should make us question whether this power is sufficient to provide the *authority* to decide how the limited resource should be used up.

Let us stipulate that in *Super-resistant Bacteria* no one is responsible for uncovering the knowledge of how to make the pill. (We shall shortly consider a case in which someone has a strong claim to have invented the drug). This leaves us with two possibilities: *First Come, First Served*, or *Common*

Ownership. The pills in *Super-resistant Bacteria* have two morally relevant important properties. First, no one can claim to have a privileged relationship to them in virtue of having invented them, second, many (perhaps all) people need them. If we take for granted the widely shared view of the equal moral status of human beings, then the salient moral question is how a group of moral equals should distribute a scarce and important resource to which none has a privileged claim.²⁰ If we start from this analysis, then the most important thing is to ensure that the way we distribute such a resource is in line with treating each person as an equal.

First Come, First Served, amounts to the claim that it is fair for those who get to the pills first to take them, and thus exclude others from the benefit. This seems like an implausible account of allocation of scarce resources among equals, as we can readily imagine scenarios in which the 100 doses of the drug go to people who do not really need them, and do not really benefit from them. Is 'I took the drug first' an adequate justification to give to those who are thereby deprived of the drug – especially those who are sickest, or would have benefited most from it?

Common Ownership provides a more plausible answer. On *Common Ownership*, the fairest response would be to view the case as similar to a version of the *Ordinary Pill Shortage* problem in which we stipulate that all human beings count equally as potential claimants of the resource, and we then work out who should be highest priority, and assign the pills to the people who have the strongest claim. It seems unlikely that merely being there first would count as a morally relevant consideration in this context. A common ownership approach may include delaying giving out the pills, if there are people in the world who will have stronger claims in the future than those people have now.²¹

Let us now examine a third scenario. We can call this *Super-resistant Bacteria with patent*.

Super-resistant Bacteria with patent

There is another new deadly disease wreaking havoc. Professor Smith designs and patents a molecule that has never existed in nature before and which can cure the disease. He takes out a patent on it. Knowledge of how to make this drug is again widespread, and there are a number of different factories in the world that could cheaply make large numbers of these pills. Due to the

20 The framing of this argument is taken from Mathias Risse's writings on the common ownership of the world. See for example, Mathias Risse, 'Common Ownership of the Earth as a Non-Parochial Standpoint: A Contingent Derivation of Human Rights,' *European Journal of Philosophy*, 2009, 17(2), 277–304.

21 I discuss time and resource allocation at length in James Wilson, 'Paying for Patented Drugs is Hard to Justify: An Argument about Time Discounting and Medical Need', *Journal of Applied Philosophy*, 2012, 29(3): 186–99.

super-resistance of the bacteria, after the hundredth person has taken their pill, the pills will no longer be effective against the disease.

Does Professor Smith have the right to auction off all the effective doses of the drug while he holds the relevant patent? Of course, if Professor Smith does this, it is unlikely that the doses will get into the hands of those who would get them under the principles that a group of moral equals would institute in common ownership cases. The key question is whether – even if we think that he should have ownership of the intellectual property in the ideas and processes for a limited period of time – this should give Professor Smith the right to use up or sell the entire world's effective doses of this drug?

It is important to clarify what the argument might be for thinking that Smith's invention of the drug gives him the right to appropriate privately the limited resource of the underlying antibiotic effectiveness. The standard view is that the justification of patents is to act as *incentives* to get inventors to act in certain ways, rather than to protect pre-existing moral claims to ownership that arise from invention. In Thomas Jefferson's words, 'Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody.'²² Standard theories of the role of patents thus do not provide support for the claim that invention brings with it moral entitlements, let alone moral entitlements over scarce and previously unowned resources that would be depleted by the industrial use of the invention.

What would be required would be an argument to establish a moral right not only to exclusively appropriate the fruits of one's intellectual labours, but also whatever other resources are necessary to profit from one's intellectual labours. I have argued at length elsewhere that there can be no moral right to exclusively appropriate the fruits of one's intellectual labours.²³ Hence I am even more sceptical that Smith could have a right to exclusively appropriate the scarce good of antibiotic effectiveness in virtue of having intellectual property rights over the drug compound.

It might be possible to argue that Smith has a claim to ownership of the effectiveness of the antibiotic that derives from somewhere else than his ownership of the intellectual property. Perhaps it could be argued that the case is similar to the case where someone mixes labour with a resource that was otherwise unowned – in this case, by turning what was otherwise merely

22 Thomas Jefferson, *Letter to Isaac McPherson*, 13 August 1813, in Writings 13: 333–5. Available online at http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html.

23 James Wilson, 'Could There Be a Right to Own Intellectual Property?', *Law and Philosophy*, 2009, 28(4): 393–427.

a molecule into a *drug* with the right pharmacodynamic and pharmacokinetic properties to be a saleable commodity.

However, there are two difficulties for making good on this analogy. First, even though the resource of antibiotic effectiveness is scarce, it is not by nature excludable (any more than other ideas are), and so it is unclear what would give the inventor the right to compel others to desist from making use of this resource. It is particularly unclear why it would be fair for Smith to exclude those who separately discovered the same resource of antibiotic effectiveness from making use of it. Second, even if someone were tempted by such an analogy, it would seem to commit us to a problematically strong view of the rights of pharmaceutical inventors. If someone had a claim to exclusive use of the effectiveness of a particular antibiotic that was separate to any claim in intellectual property, then we would not expect that claim to lapse at the point where the patent lapsed. Absent any further argument – we would expect it to be perpetual – as natural rights to physical property would be.

In view of these difficulties, I am inclined to think that the fact that Smith has invented or discovered the drug is not relevant to the question of the ownership of the resource of the drug's effectiveness. Just as in the case where no one is responsible for our knowledge of how to make the drug, we should adopt a common ownership view of the limited resource of the effectiveness of the drug.

Conclusion and policy implications

Antibiotics present us with a worldwide collective action problem. They are cheap to manufacture (especially when out of patent). Their low price brings with it a standing temptation to use them profligately, thus reducing their effectiveness for future generations. Assuming that a human life in the future is worth the same as one now, then our current use of antibiotics is deeply problematic.

The rise of drug resistance can be slowed by the appropriate use of antibiotics, but it is unrealistic to suppose that it will be halted. Even if we are careful to use antibiotics only in cases where they are medically indicated, then we will still see drug resistance rising over time.²⁴ The key question is how best to steward the limited resource of antibiotic effectiveness. The main purpose of this chapter has been to argue that antibiotic effectiveness remains the common property of humanity, regardless of who holds the patent on the relevant molecules. Owning a patent on an antibiotic does not bring with it a moral entitlement to deplete the underlying resource of antibiotic effectiveness.

24 Michael R. Millar, 'Can Antibiotic Use Be Both Just and Sustainable . . . or Only More or Less So?', *Journal of Medical Ethics*, 2011, 37: 153–7.

This conclusion should influence how we think about how to fund antibiotic research, and the pricing structure for antibiotics. I have argued that the resource of antibiotic effectiveness should not be thought of as belonging to the patent holder. This provides some, but not complete, support for the claim that we should think of antibiotic research as a public endeavour to be publicly funded for public benefit.²⁵ It also follows that we should be sceptical about attempts – such as those put forward by Kades – to argue that massively extending patent terms for antibiotics would be a plausible approach to antibiotic stewardship.²⁶ On this view, by awarding a longer monopoly period on the drugs, the patent holder – through their attempt to maximize profits – will keep the price of the antibiotic high, thus discouraging their use for trivial conditions. Kades even floats the idea that governments should auction expired patent-rights of antibiotics to the highest bidder, to prevent prices falling too low.

While such price signals would undoubtedly reduce the use of antibiotics in some low value areas, by massively extending patents on antibiotics, we would be giving the patent-owner a license to make an enormous economic rent over a period of time which would be unconnected to the length of time necessary to make a profit on their research and development investment. Insofar as we use prices as a signalling mechanism here, there seems little reason to return the excess costs that we want to impose to discourage inappropriate antibiotic use to the patent holder as profits. The resources being exploited and depleted are common, and so (absent some compelling argument to the contrary) should the benefit be. Moreover, there is something decidedly inegalitarian about controlling the usage of a common resource by charging high prices for it; in so doing, we prevent the poor from accessing it. If our aim is to combat the rise of drug resistance, it is important that any strategy also addresses under utilization of antibiotics.

To the extent we use pricing mechanisms to discourage inappropriate antibiotic usage, the tax or levies paid should be agreed at a national and international level by the WHO, and should be imposed as a tax onto healthcare systems when antibiotics are prescribed. This money could then be used for a fund to (a) provide antibiotics in a way that will be maximally effective and least likely to fuel drug resistance in poorer countries, (b) fund further research into antibiotics. Given that generic drugs make the same contribution to antibiotic resistance as branded drugs do, such a tax, if adopted, should be applied not just to makers of branded antibiotics, but to all makers of antibiotics.

25 For discussion of the funding of antibiotic research, see Michael Selgelid, 'Ethics and Drug Resistance', 2007, *Bioethics* 21(4): 218–29; Jonny Anomaly, 'Combating Resistance: The Case for a Global Antibiotics Treaty', *Public Health Ethics*, 2010, 3(1), 13–22.

26 Eric Kades, 'Preserving a Precious Resource: Rationalising the Use of Antibiotics', *Northwestern Law Review*, 2005, 99(2): 611–75.

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