June 4, 2026

House Judiciary Committee Holds Hearing on Medicines and Intellectual Property

Overview:

On June 4, the House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet held a hearing titled: "Medicines and IP: Balancing Innovation and Access." The hearing examined policies and issues around the United States patent system, generic and biosimilar drug competition under the Hatch-Waxman Act, and maintaining domestic innovation in the drug development space. The hearing featured four witnesses, two of which spoke to the need to reform the current patent framework and reduce 'patent thickets' to allow for competition. A patent thicket occurs when a company, in this case pharmaceutical manufacturers, receives numerous overlapping patents on a single product. Two other witnesses spoke to the potential consequences for biopharmaceutical innovation and national security if the patent system were to be reformed significantly, while arguing that the emergence of packet thickets has yet to slow the entry of generics and biosimilars to market in the US. Legislators on both sides of the aisle agreed to the notion that patent protections allow for innovation in brand name drugs, while generic and biosimilar competition helps to reduce overall health care costs.

Several legislative proposals were offered with the goal of balancing innovation with access to lower-cost alternatives. This includes the ETHIC Act (H.R. 3269/S. 2276) which would allow manufacturers to assert one patent per "terminally disclaimed group" against a generic or biosimilar competitor. Terminal disclaimers are legal statements that allow patent holders to relinquish part of a patent's term and are often used by holders when patent applications are rejected on the basis of obviousness-type double patenting, i.e. holding more than one patent on the same invention. The Skinny Labels, Big Savings Act (H.R. 6485 /S. 43) would provide a statutory safe harbor from patent infringement claims for generic or biosimilar manufacturers who seek to obtain approval for skinny labels of their drugs. Skinny labeling is the process in which generic or biosimilar manufacturers receive FDA approval for uses of a drug no longer protected by patents, while patented uses remain protected. The Patent Eligibility Restoration Act (H.R. 3152/S. 1546) would amend existing law by positioning specified subject matter as ineligible for patenting. Inventions would be considered to involve patent-ineligible subject matter only if they fall within specified categories, such as mathematical formulas that are not part of useful processes, mental processes performed only in the human mind, or unmodified genes that occur naturally in humans.

Interestingly, the hearing fell under the context of a unanimous Supreme Court decision in *Hika Pharmaceuticals USA Inc. et al. v. Amarin Pharma, Inc., et al.*, released shortly before questioning began. The court ruled that generics manufacturer Hika Pharmaceuticals did not infringe upon Amarin Pharma's patent while marketing generic Vascepa under a skinny label, simply for referring to the product as a 'generic version' in marketing materials without flagging limitations on approved indications under the skinny label. While the decision signified a welcome step towards increasing

generic competition, it did not extend to challenges involving the skinny labeling of biosimilars. Legislators spoke to the need for a statutory fix from Congress that would provide greater legal and regulatory certainty to manufacturers. And while Subcommittee Chair Darrell Issa (R-CA) noted that the House Judiciary Committee's jurisdiction on pressing health care matters such as pharmacy benefit manager and Medicare Advantage reform was limited, he encouraged members to seek specific issues under the current patenting system that could be modified to lower drug costs. While the hearing did not advance any specific pieces of legislation, it signals increasing focus from Congress on pharmaceutical patenting practices and opportunities for legislative reform. Of note for AMCP members, Rep. Scott Fitgerald (R-WI), quoted a statistic from the Journal of Managed Care and Specialty Pharmacy on patient's prescription abandonment rates when cost sharing arrangements exceed $100.

Committee Leadership:

- Full Committee Chair – Jim Jordan (R-OH)
- Full Committee Ranking Member – Jamie Raskin (D-MD)
- Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet Chair – Darrell Issa (R-CA)
- Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet – Hank Johnsdon (D-GA)

Witnesses

- Krista Carver, Partner, Covington & Burling
- Michael Carrier, Board of Governors Professor, Rutgers Law School
- Rachel Goode, Senior Vice President and Head of Legal and Intellectual Property, Fresenius Kabi
- Jamie Simpson, Chief Policy Officer and Counsel, Council for Innovation Promotion

Question and Answer Highlights:

Subcommittee Chair Darrell Issa (R-CA) – Tod

Rep. Scott Fitzgerald (R-WI) – Recent research shows that 100,000 million prescriptions are abandoned by patients due to cost. The Journal of Managed Care and Specialty Pharmacy found that increased cost sharing above $100 is associated with a 75% abandonment rate for certain specialty drugs. Cost is the prevailing thing for patients purchasing. We don't want to block access to lifesaving therapies. Do you believe reforming patent law vs market based solutions could be an effective way for lower prices?

Dr. Goode – These drugs need to get on the market in the first place, that's what patent reform is about. The market can't evolve around patent system abuse. You need generics on the market. The ETHIC Act would bring drugs to market sooner. We have peer-reviewed data that links patent thickets to delayed access to generics.

Rep. Fitzgerald – Are there other benefits the ETHIC act could result in?

Dr. Goode – The ETHIC Act is pro innovation. Pharma should innovate new uses for drugs. If a drug had 50 patents, 20 can duplicative and 30 unique. Under the ETHIC Act, manufacturers could still litigate the 30 unique patents. With more patents that innovate, there more patents to litigate. The Ethic Act discourages spreading out duplicate patents and encourages unique patents.

Rep. Fitzgerald – A trial for new treatments takes years. If the Ethic Act is signed into law, what behavioral changes would pharma make?

Ms. Carver – The ETHIC act would harm innovation. Generics and biosimilars would abuse rightful patents. It would allow gamesmanship, manufacturers would have to pick from patent group. My view is it would undermine innovation.

RM Johnson – The USPTO rejects follow on applications from earlier versions, it may grant patents in terminal disclaimers. Doesn't a patent have to demonstrate a patent is new, useful and non-obvious from prior art?

Dr. Goode – Yes. Once the patent owner starts filing new patents, they find duplicates. The duplicates add nothing more.

RM Johnson – Some patents can receive a patent that is an obvious variant, as long as a terminal disclaimer is filed. How is this different than what Dr. Goode said?

Ms. Simpson – The version of terminal disclaimer described is an oversimplification. Terminal disclaimers are an agreement to give up a patent term in a second patent has an overlap. You can have two different patents if there is a small overlap. They are a valuable tool for the patent office to monitor patent prosecution. These patents are not duplicates, which is why the ETHIC Act goes further than described/intended.

RM Johnson – Total R & D expenditures are over $6 billion before the first patient is prescribed. Most drug candidates don't become approved, correct?

Ms. Simpson – That's right and it's an interesting feature of the market; the only way drug companies can afford to take bets is to rely on strong patents for drugs that do.

RM Johnson – Ms. Carver, what role do patents play in giving companies stability to make substantial investments?

Ms. Carver – Patents are crucial to enabling companies to make investments. The failure rate is high for medicines in clinical trials. Patents provide an opportunity to recoup R & D costs and bring new therapies to patients. Pharma companies have invested $100 billion in R & D in the past decade.

Rep. Laurel Lee (R-FL) – Americans want access to medication and innovation. We shouldn't choose one over another, but ensure Congress delivers on both. There is a shared recognition that patients benefit when new treatments develop. Since Congress enacted Hatch-Waxman, which components have been successful in increasing access to lower cost medicine?

Ms. Simpson – The law created a balance between resecting innovators and resolving disputes. It's been particularly effective because it encourages disputes to be litigated in one forum.

Ms. Goode – It worked well for the first few decades. In the last ten years patent thickets have become an entrenched issue. Right now, the litigation framework is not cut out which is why were seeing delays.

Rep. Lee – How important is regulatory or legal certainty for companies?

Dr. Goode – It cost eight years to make a biosimilar. When we start biosimilar development, we're only looking at a few patents but see many a few years into development. It makes it difficult for companies who need business certainty. If you have a volatile system, it makes launching and manufacturing more difficult.

Ms. Simpson – Hatch-Waxman doesn't matter for how many patents one has. What typically happens, the scope of the dispute will narrow, a judge will require claims to be litigated before a jury. What data shows is the period of exclusivity is 12-14 years. If there is an increase in patent thickets, it hasn't changed when generics get on market.

RM Raskin – Dr. Goode you believe there should be one patent per cluster? If all the litigation could be done in one day you'd have no objection?

Dr. Goode – Not exactly, these patents can be issued during litigation after litigation,

RM Raskin – Your problem is you don't want this to be used as an excuse to allow for monopoly control over the original patent. If there was a process to reduce that time, you'd have no problem?

Dr. Goode – We like the unique patents, innovative ones. It helps us. Under the ETHIC Act that would continue.

RM Raskin - Ms. Simpson, does that work for you?

Ms. Simpson – I think that's oversimplifying what goes on with terminally disclaimed patents. There are a number of issues here in terms of serial litigation. The main point is that the procedure benefits the office in making it easier to go through a big patent application in smaller pieces. With no real data showing the number of patents and how long it takes to get generics to market, there is no real problem here.

RM Raskin – Will you tell us how the patent dance works?

Ms. Carver – Sure, the patent dance refers to the patent provisions of the Biologics Price Competition and Innovation Act in 2010. First, a biosimilar manufacturer has to provide the reference sponsor with their application manufacturing info. Reference sponsor has to provide list of patents that could be infringed by the biosimilar product. Supreme Court found this provision to be voluntarily, now we see companies opt out entirely which undermines purpose of patent dance.

RM Raskin – So what alternatives are available?

Ms. Carver - If the company doesn't know what might be infringed, they have to bring suit on those ones they assume are infringed.

RM Raskin – So you think it should be a mandatory dance?

Ms. Carver – Yes.

Rep. Russell Fry (R-SC) – What do you make of the recent Supreme Court decision that just came out?

Mr. Carrier – It's a positive decision that makes clear that certain types of conduct do not lead to induced infringement. But there is a different rule for Congress to play. The Supreme Court cannot act with the certainty congress can. Supreme Court also applied to one context, not biosimilar context.

Rep. Fry – You discussed major changes to patent laws in the 80s and 2010s, and that investment shifted from Europe to the US. How has balancing patent rights and generic competition affected US investment in biopharma?

Ms. Simpson – These laws transformed the US into a place that attracts investment. Since the 1980s, Congress and the courts have dramatically weakened patent law. We might not see the effects yet but it's providing an opportunity for other countries to take the lead. China has filled this void, strengthening its patent law and investing money. Our country relies on the patent system to fuel investment.

Rep. Fry – Do you think our patent system is too restrictive?

Ms. Goode - With the ETHIC Act being pro investment. Terminal disclaimers make it easy to flood the market with duplicative patents. When we think about China, we should think about the quality of American patents.

Rep. Fry – What role does IP policy play in promoting competition? Versus other fixes like regulating PBMs or insurers?

Mr. Carrier – The pharmaceutical system is complex and there is more than enough blame to go around. The Hatch-Waxman Act was designed to be a comprise for promoting brand investment and generic competition. We're trying to restore this balance.

Rep. Fry – Do you believe that pharmaceutical companies have used Hatch-Waxman to game the system?

Mr. Carrier – Yes. It's been successful but also has been gamed. Hatch and Waxman say this themselves.

Rep. Zoe Lofgren (D-CA) – I was glad to introduce the Skinny Labels, Big Savings Act to get lower cost generics to patients sooner. A skinny label allows a generic company to compete for uses of a drug no longer under patent while leaving patented uses protected. Would this bill add certainty?

Mr. Carrier - Absolutely, certainty is needed. Even though the Supreme Court decision was possible, it doesn't give the certainty that congress can give.

Rep. Lofgren – Would the skinny labels bill restore certainty to get generics to patients sooner?

Dr. Goode – Yes, it puts a safe harbor around the label itself. It rewards good behavior, incentivizing generic manufacturers to stay away from marketing patented uses.

Rep. Ben Cline (R-VA) – the Supreme Court ruling is not a safe harbor. Generics have saved payers trillions over the past decade. But the decision does not reach biosimilars, our skinny labels bill does. The statue that we need provides durability. A generic company has to demonstrate therapeutic equivalence, right?

Ms. Carver – Yes, therapeutic equivalence is demonstrated in the FDA orange book. There is a question on whether a label does or does not mention patented use. It's FDA reviewing the labeling of a generic. They are not equipped to determine if labeling induces patent infringement. We also need to incentivize new uses of existing drugs.

Rep. Cline – Does the court decision give the certainty that statute would?

Ms. Simpson – It doesn't give you the certainty, but the bill would do more harm than good.

Rep. Cline – Why doesn't a favorable ruling give generics the certainty need? What would codifying the carve out do that the ruling does not?

Mr. Carrier – Amarin said in oral arguments that it'll just file another complaint. Congress can provide the certainty that courts can't.

Rep. Deborah Ross (D-NC) – My district is home to a vibrant life sciences and biotechnology sector. Our nation's robust patent system is the foundation of this success. There is a consequence of weakening patent system can lead to national and economic insecurity. Could you expand on the consequences of innovation moving overseas?

Ms. Simpson – It's a huge concern if the biopharmaceutical industry were to move overseas. Security risks would be confounded if an adversary like China controls all the drugs. A lot of what we're talking about is death by a thousand cuts to the industry. The skinny label bill would undermine one of the last protections companies have to do research here. I think this is a step we should not take.

Rep. Lance Gooden (R-TX) – Some argue that patent thickets are non-existent myths. Could you explain that?

Mr. Carrier – When you collect a bunch of patents and use it in an abusive way, it's a problem. On terminal disclaimers, there was an eye disease drug which faced patent litigation. Amgen claimed its drug had a component that did not infringe, which the court allowed. Regeneron came back the next day with patent and a new terminal disclaimer and filed an additional lawsuit. This is about playing games with terminal disclaimers.

Ms. Simpson – One thing to consider with repetitive lawsuits is that courts have doctrines to deal with repetitive lawsuits, like issue preclusion. If courts aren't dismissing on these grounds, it means these claims aren't duplicative. I don't think there's a real problem to be solved that the courts can't deal with.

Rep. Gooden – Would you agree that current patent law makes it easy for brand manufacturers to prevent generics and biosimilars from entry. Would you agree?

Ms. Simpson – I would not. Data shows that generics enter the market on 12-14 years, less than the length of a patent.

Dr. Goode – There was a patent on drug purification, which was not new and cancelled. A one-word difference, "directly," allowed the patent to be relitigated. The ETHIC act doesn't weaken patents, it encourages unique patents and stops clogging the system with repetitive patents.

Chair Issa – Isn't it true that biosimilars take 20-21 years for entry?

Ms. Simpson – The data I've seen suggests 14 years.

Dr. Goode – Old data shows 14 years or less, going back to 1984. The latest data from 2026 shows it took 18 years for biosimilars. Congress allowed patent term extension only up to 14 years.

Rep. Kevin Kiley (I-CA) – There's a lot to be optimistic about. Whatever the number of years it is, if there was no original innovator, how would a generic come along?

Ms. Simpson – Exactly, that's why we need a branded industry to begin with.

Rep. Kiley – If we didn't have patent protections, I suppose you could use trade secret law to protect brands. How would that affect generics?

Ms. Simpson – That's right, the patent system promotes disclosure, rather than what trade secrets would do. There is no time limit on trade secrets as opposed to patents.

Rep. Kiley – Subject matter eligibility is also an issue. I've sought to address this through the Patent Eligibility Restoration Act. Can you give us insight into this issue?

Ms. Simpson – This is an important issue. The Supreme Court made changes to patent eligible subject matter which has impacted several industries. It's not clear whether diagnostics have patent protection in the US. There's a risk we lose industries to other countries with better protections.

Chair Issa – The ETHIC Act was alluded to several times. If we narrowed the act to require all claims be brought at one time. Would that be a partial conclusion? Would there be any unfairness?

Dr. Goode – That's bad for innovation, we want branded companies to innovate new uses for branded drugs.

Chair Issa – I mean all known at one time.

Dr. Goode – It over complicates the case when you go from five to 70 patents, as has been the case. Federal courts can't handle this number, which slows a case down for years.

Chair Issa – We're dealing with the unanimous Supreme Court ruling released a few minutes ago. Would you say that the history of doctors prescribing off patent is a huge part of innovation, and what pharma takes credit for is because of doctors?

Dr. Goode – Skinny labels have been available for four decades, but innovation continued.

Mr. Carrier – Absolutely, states had substitution laws even before Hatch-Waxman.

Chair Issa – We've said a lot about competitiveness. If the US market is the most excluded market for generics, are we doing ourselves a favor or excluding the development of these products while foreign consumers get the product sooner?

Dr. Goode – Because our system is so volatile, Americans get access to cheaper drugs later and less manufacturing can happen in the US.

Mr. Carrier – Generic competition is crucial but so is innovation, so I'd consider them together.

Ms. Simpson – I'd say it's a problem to our competitiveness.

Ms. Carver – America is doing a great job balancing innovation and access compared to other countries.

Hearing recording:

- https://judiciary.house.gov/committee-activity/hearings/medicines-and-ip-balancing-innovation-and-access