IN THE SUPREME COURT OF SOUTH AFRICA

CASE NO: 138/12

In the matter between:

AVENTIS PHARMA SA	First Appellant / Patentee
SANOFI AVENTIS SA (PTY) LTD	Second Appellant
WINTHROP PHARMACEUTICALS (PTY)	Third Appellant
and	
CIPLA LIFE SCIENCES (PTY) LTD	First Respondent
CIPLA MEDPRO (PTY) LTD	Second Respondent
MEDPRO PHARAMCEUTICA (PTY) LTD	Third Respondent
TREATMENT ACTION CAMPAIGN	Amicus Curiae

HEADS OF ARGUMENT – AMICUS CURIAE

INTRODUCTION

1. The purpose of the Treatment Action Campaign's participation in these proceedings is to address the protection of the rights of people in need of medicines in interim interdict proceedings concerning alleged pharmaceutical patent infringements. The TAC is concerned primarily with the rights of poorer members of our society whose access to health care services, whether in the public or private sectors, is in large part dependant upon the availability of

affordable medicines. The concern is both with current and potential users of pharmaceutical products.

2. The patent in issue in these proceedings relates to a drug effective in treating various forms of life-threatening cancer – docetaxel. Docetaxel is not, itself, subject to any patent. Its patent expired in 2007.[1] The disputed patent, which will expire next year, relates to a *composition* of unpatented products, which – when mixed – facilitate the intravenous administration of docetaxel.

3. The validity of the patent is the subject of a dispute to be determined at trial. Respondents allege it is invalid because it is not clear, because its subject matter was not novel and did not entail an inventive step and because a material false representation was made in the application.

4. Because South Africa's system of patent registration does not require *substantive* examination of claims before a patent is granted, the Court's function when adjudicating disputes about a patent's validity is critical. In essence, the Court is likely to be conducting the first substantive assessment of whether the patent complies with South Africa's substantive requirements for protection. In some countries, such as India, the United States, Brazil, the 36 contracting states to the European Patent Convention and the 18 member states of the African Regional Intellectual Property Organisation,[2] substantive examination occurs prior to the grant of a patent. It is thus relatively easy to register patents in South Africa under the Patents Act 57 of 1978.

[1] Vol 1, p.14, para 12.2, Kugel.
[2] Examination ordinarily takes place by ARIPO.

5. In these submissions, we deal first with the duties the Constitution imposes on courts to protect the rights of people in need of medicines and then with three of the four requirements for an interim interdict: a clear or *prima facie* right, the balance of convenience and alternative remedies. We refer to international and foreign law, including US and Indian law.

6. In summary, we make the following submissions:

6.1. The Patents Act, like any other statute, must be construed consistently with the Constitution. This requires Courts to balance the rights of any patentee with the rights of those who need access to medicines, which are protected in section 27 of the Constitution. The need to balance these rights affects how the Court must interpret and apply the provisions relied upon by the parties. Given the possible invalidity of the patent in issue in these proceedings, the rights of people living with cancer loom large.

6.2. Courts are under a constitutional duty when considering the balance of convenience in interim interdict proceedings, to assess whether the grant of an interdict will unreasonably limit the rights of people who require access to medicines, in this case people with cancer. A party seeking to interdict the supply of medicines must prove to the Court that the interdict will not harm the public interest. This, we submit, is what the Constitution requires. It is also consistent with international law principles, and the approach is in line with a

growing body of case law in comparative jurisdictions including the USA, where patent protection is strong, and India, which, like South Africa, is faced with very serious public health challenges.

6.3. Because the appellants regard the rights of people with cancer as irrelevant, the Court has not been furnished with adequate evidence upon which it can assess whether the rights of people with cancer will be harmed if an interdict is granted. The appellant has not sought to discharge the onus of proof we submit it must discharge. Nevertheless, if regard is had to all evidence on record including such evidence that might be regarded as relevant and in either parties' favour, we submit that it is probable that the rights of people living with cancer will be unreasonably and unnecessarily limited if an interim interdict is granted.

6.4. Finally, we submit that, in line with developments in the USA and India, the Court must assess in each case whether a party seeking an interdict might have a satisfactory alternative remedy in damages. In this case it is difficult to see why damages cannot be regarded as a reasonable alternative remedy.

THE COURTS' DUTIES TO PROTECT PATIENTS' RIGHTS

7. The Court's duty to protect the rights of people in need of medicines flows from section 39(2) of the Constitution read with section 27, the right to have access to health care services.

8. Section 27 of the Constitution provides that everyone has the right "*to have access to health care services*". Section 27 has been interpreted by the Constitutional Court to include the right to have access to medicines. Amongst others, the State has an obligation to ensure the affordability of medicines and to create an environment in which medicines of proven quality, safety and efficacy are available.[3] Section 27 is a right closely connected to the right to dignity with particular resonance for those living in poverty, as so many do in South Africa: "*Abject poverty wrenches dignity out of any life. Access to affordable medicines is an important component of any scheme directed at poverty reduction and the physical well-being of our people.*"[4]

9. Section 39(2) of the Constitution requires courts to promote the spirit, purport and objects of the Bill of Rights when interpreting legislation[5] and when developing the common law.[6] Courts enjoy "*no discretion*" in this regard and these duties "*must always be borne in mind*" irrespective of the pleadings.[7] In consequence, when interpreting the Patents Act, the court must observe section 39(2). Similarly, when considering and applying the common law relating to the grant of interim interdicts, section 39(2) must be observed.

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[3] *Minister of Health v New Clicks SA (Pty) Ltd and others* 2006 (2) SA 311 (CC) at paras 84 and 314 (per Chaskalson P), paras 514 and 525 (per Ncgobo J) and paras 705 to 706 (per Moseneke J)
[4] *New Clicks* para 705 per Moseneke J.
[5] The leading authorities on interpretation of legislation are *Investigating Directorate: Serious Economic Offences and Others v Hyundai Motor Distributors (Pty) Ltd and Others: In re Hyundai Motor Distributors (Pty) Ltd and Others v Smit NO and Others* 2001 (1) SA 545 (CC) at para 26 and *Wary Holdings (Pty) Ltd v Stalwo (Pty) Ltd and Another* 2009 (1) SA 337 (CC) at paras 46, 84 and 107, the latter imposing a duty to adopt the interpretation that best promotes the Bill of Rights even if neither interpretation will result in invalidity of a statute.
[6] *Phumelela Gaming and Leisure Limited v Grundlingh and Others* 2007 (6) SA350 (CC), paras 26 – 27
[7] *Phumelela,* paras 26 to 27

A CLEAR OR PRIMA FACIE RIGHT

Introduction

10. The Patents Act has not to date been interpreted "through the prism of the Constitution". An analogous exercise was conducted by the Constitutional Court in *Laugh It Off*[8] in which section 34(1)(c) of the Trade Marks Act 194 of 1993 (the anti-dilution provision prohibiting *inter alia* tarnishment of a trade mark) was interpreted in light of the right to free speech. The Constitutional Court firmly rejected what it termed a two-stage approach, which entailed an anterior application of section 34(1)(c) *before* considering if the free speech guarantee had been infringed.[9] It held that a two-stage approach "*in effect prevents an understanding of the internal requirements of the section through the lens of the Constitution.*" Rather, the right to free speech must be protected both in the manner in which the section is interpreted and the manner in which facts arising in a particular case must be applied to the law. In each case the interests of the owner of the marks must be balanced against the claim of free expression.[10]

11. Similar considerations apply when interpreting the Patents Act. The Court must interpret its provisions and apply the facts to the law in a way that appropriately balances the rights of a patentee with others' constitutional rights.

[8] *Laugh It Off Promotions CC v SAB International (Finance) BV* 2006 (1) SA 144 (CC).
[9] See para 43.
[10] See para 44

Interpreting the Patents Act through the prism of the Constitution

12. Because section 45(1) of the Patents Act creates exclusive rights, which are exceptional, it must be justified.[11] The exclusive rights are very powerful indeed, entitling the holder to an extended monopoly. The statutory monopoly that is granted to a patentee has been held by this Court to be a "*means of encouraging inventors to put their inventions into practice because by this means they obtain the financial rewards their inventive gifts warrant*".[12] However, the Court also noted that "an essential *quid pro quo* of the theory" is that the "*benefit to the public … is served*."[13] The broad purpose of the patent system has also been described extra-curially by Cameron J, writing with Berger, as being intended to "*pursue innovation and subsequent commercialization*" in the public interest.[14] Indeed, the authors describe a patent as a 'liberty-infringing privilege'.

13. While the purposes served by patent protection are legitimate public purposes, the Patents Act must be interpreted and applied to ensure the public interest in patent protection is in fact served and ensuring other rights are not unreasonably limited thereby. In the case of medicines, section 27 is implicated because a medicine may be unavailable or because it may be unaffordable, often as a result of the patent.

14. Various provisions of the Patents Act are designed to ensure that the rights of patent holders are not exercised unreasonably to preclude access to knowledge and

[11] Harms L, "Intellectual property Litigation under the Common Law System" [2004] *EIPR* at 488.
[12] *Syntheta (Pty) Ltd (formerly Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 1999 (1) SA 85 (SCA) at 88I
[13] Ibid at 88I-J.
[14] Cameron E and Berger J, "Patents and Public Health: Principle, Politics and Paradox" (2005) 131 *Proceedings of the British Academy* 331 at 345.

products. While mindful that this Court cannot prejudge the constitutional validity of its provisions, at a general level, mechanisms to dispute the validity of a patent are crucial to protecting rights such as section 27 rights.

15. The respondents' defence of lack of clarity[15] protects not only patentees and competitors but the public generally. The test is whether a patent is reasonably certain.[16] Arguably the test ought to be stricter under the Constitution, but crucially, when applying the test courts must be astute to ensure that the public purposes of the section are advanced. Commercially of course, potential competitors need to know the limits of the field that is closed to them.[17] The public purposes might be viewed as two-fold. First, part of the *quid pro quo* represented by the patent is that knowledge about innovation is placed in the public realm so as to advance further innovation and to enable the invention to be worked by competitors in due course.[18] So the patentee must meet its part of the bargain. Secondly, the lodgment of ambiguous claims can confuse competitors and deter the bringing of products to market and thus compromise access.[19] It can also encourage overzealous attempts at their enforcement, which can also limit access especially when interim relief is sought and granted.[20]

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[15] Based on section 61(1)(f)(1) of the Patents Act
[16] *Letraset Ltd v Helios Ltd* 1972 (3) SA 245 (A) 250B-C
[17] *Letraset* supra at 249F and G .
[18] *Letraset* supra at 249E – F; and see s32(3)(b) of the Patents Act which deals with the requirements of complete specifications and the purpose of requiring knowledge to be in the public realm.
[19] A similar point is made in *Gentiruco AG v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A) at 612E-F.
[20] See the remarks of the Kenyan High Court, Nairobi, in *Ochieng and Others v the Attorney General,* Petition 409 of 2009, to date unreported decision delivered only in April 2012, at para 84 on the impact of ambiguity in a statute dealing with counterfeit goods on the importation of generic medicines.

16. The requirement of clarity must be carefully evaluated factually as it serves to ensure that access is not unnecessarily limited. If, on a proper construction, a claim is ambiguous, a court need not be astute to give it some meaning in order to rescue it from invalidity; on the contrary, the court's "*bounden duty*" is to hold it invalid.[21]

17. Similarly, the requirements that only new inventions and inventions involving an 'inventive step' be patented serve the public interest. Unless there is careful scrutiny of the novelty and inventiveness of the subject matter of a patent, the very purpose of its protection may be defeated and simultaneously access may unnecessarily be limited.

18. As we emphasise above, South African courts perform a particularly important role in evaluating the validity of patents, and thus in protecting section 27 rights, because there is no substantive pre-grant examination of patents.

An international perspective

19. The need to balance innovation with access, contemplated by the Constitution, has been referred to as 'the principle of balance' and underpins the statutory protection of patents globally, albeit in different ways.[22]

20. Under international law, insofar as the right to health is concerned, the principle of balance finds expression in the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights ("the TRIPS Agreement"), read with the WTO's *Declaration on the TRIPs agreement and public health* ("the Doha

[21] *Gentiruco* at 616A-C.
[22] See Cameron and Berger supra at 345.

Declaration").[23] The Doha Declaration makes it plain that the TRIPS Agreement – which, amongst other things, requires WTO members to legislate certain minimum standards of protection for all new inventions – "*can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all*".[24] In addition, the Doha Declaration recognises that the TRIPS Agreement "*does not and should not prevent [WTO] members from taking measures to protect public health*". These international principles are consistent with the court's duty to interpret the Patents Act to promote access to medicines. They also inform the duty on courts when applying and developing the common law of interim interdicts.

BALANCE OF CONVENIENCE

The attitude of the parties

21. Contrary to appellants' assertion,[25] there is substantial authority to the effect that the public interest is relevant to assessing the balance of convenience. Appellants rely on *Bress Designs*[26] to assert the contrary, which though an intellectual property law case, does not reflect the law today and, in any event, is indefensible under the Constitution. The respondents submit the public interest and constitutional rights are relevant to an assessment of the balance of convenience but do not analyse the case law.[27]

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[23] WTO Res. WT/MIN(01)/DEC/2, 4th Sess., Ministerial Conference, 20 November 2001
[24] Ibid at paragraph 4.
[25] Para 55(a) of the heads of argument
[26] *Bress Designs (Pty) Ltd v GY Lounge Suite Manufacturers (Pty) Ltd and another* 1991 (2) SA 455 (W) at 476B-G
[27] See respondents' heads of argument, para 8.1, fn 6. Reference is made to Herbstein and Van Winsen, *The Civil Practice of High Courts of South Africa* 5ed vol 2 1473 "*and the cases cited at footnote 127"* . These cases include the following: *Roberts v Chairman Local Road Transportation*

South African authorities

22. We have considered the authorities referred to and sourced others. We summarise briefly what they show.

23. First, various High Courts regard the public interest as relevant to the balance of convenience. There are at least three such Cape High Court reported decisions, the public interest discerned in part by the interests served by legislation in issue.[28] The Cape precedent was followed in *Verstappen v Port Edward Town Board*[29] clarifying the oft cited dictum in *Olympic Passenger Service*[30] that "*by balance of convenience is meant the prejudice to the applicant if the interdict be refused weighed against the prejudice to the respondent if it be granted*." The public interest was treated as relevant to the balance of convenience in Natal in *Marinpine Transport (Pty) Ltd v Local Road Transportation Board, Pietermaritzburg*.[31] The same principle has been adopted by the Competition Appeal Court in *Glaxo Wellcome*,[32] which followed

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Board, Cape Town (2) 1979(4) SA 604 (C) at 607F-G, 608D; *Bamford v Minister of Community Development and State Auxiliary Services* 1981(3) SA 1054 (C) at 1061D-E; *Marinpine Transport (Pty) Ltd v Local Road Transportation Board, Pietermaritzburg* 1984(1) SA 230 (N) at 234E-G; *Verstappen v Port Edward Town Board* 1994(3) SA 569 (D) at 576H-J; *Sema v Minister of Safety and Security* 1995(2) SA 401(O) at 405B-E, 406I-J; *Cherry v Minister of Safety and Security* 1995(3) SA 323 (SE) at 338E-H; *Batista v Commanding Officer, Sanab, SA Police, Port Elizabeth* 1995(4) SA 717 (SE) at 723HiI; 725E-H; *Ynuico Ltd v Minister of Trade and Industry* (1995) 11 BCLR 1453 (T) at 1473G-1474C.

[28] These being *Bamford v Minister of Community Development and State Auxiliary Services* 1981 (3) SA 1054 (C) at 1061D-E; *Corium (Pty) Ltd v Myburgh Park Langebaan* 1993(1) SA 853 (C) at 858E-G; and *PS Booksellers (Pty) Ltd and another v Harrison and others* 2008 (3) SA 633 (C) at para 104. In *Bamford,* the applicant asserted a public interest whereas in *Corium* the court considered the public interest independently of the interests of the parties. The decision of *Roberts v Chairman Local Road Transportation Board, Cape Town and Another (2)* 1979 (4) SA 604 (C) at 607F-G, 608D deals with a section 49(11) application.

[29] 1994 (3) SA 569 (D) at 576H.

[30] *Olympia Passenger Services (Pty) Ltd v Ramgalan*1957(2) SA 382 (N) at 383F-G.

[31] 1984 (1) SA 230 (N) at 234E-G.

[32] *Glaxo Welcome v Terblanche NO (No 2)* 2001 (4) SA 901 (CAC) at 910A-F.

Verstappen. *Verstappen* and *Glaxo Wellcome* were relied on to similar effect in *Uncedo Taxi Service Association v Nelson Mandela Bay Municipality.*[33]

24. Secondly, in *Pikoli v President of the RSA*,[34] the public interest was considered but under the requirement of irreparable harm, not the balance of convenience.

25. Thirdly, the public interest is a consideration relevant to interim relief pending the determination of proceedings relating to the validity of legislation.[35]

26. Fourthly, this Court has considered the public interest and constitutional rights in the context of interim interdicts restraining publication. In *Hix Networking Technologies v System Publishers (Pty) Ltd*,[36] the Court held that the balance of convenience will often be the appropriate place to consider the impact on the limitations of rights. *Midi Television (Pty) Ltd t/a E-TV v Director of Public Prosecutions*[37] confirms the *Hix* holding that the principles of interim interdicts can ensure that the freedom of the press (which is concerned not only with the interests of publishers but of all who access information) is not unduly abridged.

27. There is thus substantial authority in the post Constitutional era to the effect that the public interest is an important consideration in applications for interim relief, usually

[33] Unreported decision found at [2008] JOL 22141 (SE) at para 12
[34] 2010(1) SA 400 (GNP) at 409F-G.
[35] There is a long line of cases on this point under the interim Constitution. By way of example, we refer to *Cherry v Minister of Safety and Security* 1995 (3) SA 323 (SE) at 338E-H.
[36] 1997(1) SA 391 (A) at 402D.
[37] 2007(5) SA 540 (SCA) at paras 19 and 20.

when considering the balance of convenience. We submit that this approach is consistent with section 39(2) of the Constitution.

Comparative Law

Introduction

28. Recent developments in the United States and India are instructive. The public interest has become an important factor in both jurisdictions in interim injunctions applications relating to pharmaceutical patent infringement proceedings.

29. The US Supreme Court decision in *eBay Inc v MercExchange LLC*[38] has provided the impetus for the development in both jurisdictions. The Supreme Court held that the ordinary test to be applied to the grant of a permanent injunction applies equally in intellectual property cases. It rejected a rule hitherto applied by the Court of Appeals for the Federal Circuit to the effect that "*courts will issue permanent injunctions against patent infringement absent exceptional circumstances.*" One leg of the test for an injunction in the US is if the public interest will be disserved by its grant.

The United States

30. The US is a useful comparator because its system offers strong protection of intellectual property rights. Its federal Constitution does not protect socio-economic rights; neither has it been interpreted to impose positive obligations on government regarding the realisation of those rights that are protected.[39] However, its rules on

[38] 126 S. Ct 1837 (2006).
[39] *DeShaney v. Winnebago County Department of Social* Services 489 US 189 (1989)

injunctions require consideration of the public interest and thus the social impact of decisions.

31. The *eBay* rule applies both to final and temporary injunctions:[40] the difference lies in that a plaintiff must show a likelihood of, rather than actual, success on the merits. For a temporary injunction, a party must establish a likelihood of success, that irreparable harm will be suffered in the absence of preliminary relief, that the balance of equities tips in its favour and that the public interest would not be disserved by its grant.

32. A number of courts post *eBay* have addressed the public interest factor in intellectual property disputes. We refer to four cases of which we are aware in which injunctions have been refused: *Innogenetics NV v Abbott Laboratories,*[41] *Bard Peripheral Vascular Inc v WL Gore & Associates Inc*,[42] *Johnson & Johnson Vision Care Inc v Ciba Vision Corp*[43] and *Edwards Lifesciences AG v CoreValve Inc*.[44]

33. Various general observations can be made. First, different public interest considerations will inevitably arise in each case. Secondly, while injunctive relief may be particularly inappropriate where a product is life-saving, it may be inappropriate

[40] *Perfect 10, Inc. v Google, Inc.* 653 F.3d 976 (9th Cir. 2011) at 981. The appellant's petition for a writ of certiorari was denied by the Supreme Court on 5 March 2012.
[41] 578 F. Supp. 2d 1079 (W.D. Wis. 2007). Innogenetics sued Abbott Laboratories alleging that the latter had infringed its patent for a method of genotyping the hepatitis C virus. The jury found that the patent had been infringed. On a consideration of a hypothetical negotiation for a licence, it determined that Abbott should pay an amount in damages which included a running royalty per diagnostic test that had already been sold.
[42] 2009 WL 920300 (D. Ariz. Mar. 31, 2009); 2009 U.S. Dist. LEXIS 31328 (D. Ariz. 2009) Bard sued Gore & Associates for infringement of a patent for a prosthetic vascular graft. Finding infringement, the jury awarded Bard damages that included both lost profits and a reasonable royalty.
[43] 712 F. Supp. 2d 1285 (M.D. Florida 2010).
[44] C.A. No. 08-91-GMS (Dist. Court, D. Delaware 2011).

even where the consequences of its unavailability are 'less grave'. Thirdly, the US Courts are astute to ensure that the party who seeks injunctive relief meets its onus to prove that an injunction will not harm the public interest. In *Innogenetics*, the Court referred that particular issue to oral evidence rather than determine the matter on paper because of its importance.

34. In *Innogenetics* the Court recognised that an injunction could "*pose a serious risk to the public health if [the] plaintiff cannot fill the diagnostic market need*". Although the plaintiff had demonstrated all requirements for an injunction save for the public interest requirement, the Court scheduled an evidentiary hearing rather than decide that important question on a paper record. At the evidentiary hearing, the plaintiff would "*bear the burden of proving by the preponderance of the evidence that the needs of the Hepatitis C diagnostic market could continue to be met if an injunction issued against defendant*".[45] On appeal, the permanent injunction granted by the trial court was overturned.[46]

35. In *Bard Peripheral Vascular***,** dealing with a patent relating to prosthetic blood vessels that are used to bypass or replace blood vessels, an injunction was refused in light of the public health consequences. The decision was affirmed on appeal in the Court of Appeals for the Federal Circuit.[47]

36. In *Johnson & Johnson Vision Care*, a federal district judge declined to grant a permanent injunction following a finding that a particular contact lens product

[45] At 1105.
[46] *Innogenetics, NV v. Abbott Laboratories*, 512 F. 3d 1363 (Fed. Cir. 2008).
[47] *Bard Peripheral Vascular Inc v WL Gore & Associates Inc* 2010-1510 (Fed. Cir. February 10, 2012); 2012 U.S. App. LEXIS 2612

infringed patents owned by CIBA Vision Corporation.[48] The dismissal of the motion was based on the public interest, notwithstanding that the products were not lifesaving. The Court regarded the 'deleterious effects' of an interdict on the public as 'too great to permit' and the matter turned on the failure of the party seeking an injunction to meet its onus.

37. In *Edwards Lifesciences,* a federal district judge dismissed a motion for an injunction to prevent the continued infringement of a patent relating to a medical device used in the treatment of a disease of the heart valves. Implicit in the decision is a recognition that an injunction will only be granted if it is in the public interest to do so.[49] An appeal is pending before the Court of Appeals for the Federal Circuit.

India

38. India recognises health care as a justiciable constitutional right (albeit not on all fours with section 27). The right to health in India derives not from an express right to health care but from Article 21 which protects life and personal liberty.[50] As noted above, in contrast to South Africa the Indian Patent Act 1970 makes provision for substantive patent examinations.[51]

[48] Middle District of Florida (Jacksonville Division)
[49] At page 29 of the typed judgment
[50] Article 21 provides as follows: "No person shall be deprived of his life or personal liberty except according to procedure established by law." Article 21 has been interpreted by the Indian Supreme Court, in *Bandhua Mukti Morcha v Union of India and Others* 1984 AIR 802; 1984 SCR (2) 67 at para 2 to include the protection of the right to health.
[51] Chapter IV, sections 12 to 24.

39. We have sourced authorities from two prominent High Courts in India (Bombay and Delhi) in which interim interdicts have been refused in pharmaceutical patent infringements in light of the public interest and Article 21. The balance of convenience is the relevant consideration.

40. In *F. Hoffmann-La Roche Ltd and Another v Cipla Limited*,[52] the Delhi High Court considered an application for an interlocutory injunction in respect of the anti-cancer drug erlotinib (marketed as Tarceva) pending the outcome of an action for a permanent injunction and damages. At the time, the respondent planned to launch a generic version of the drug in India as well as to manufacture it for export. In denying the injunction, the court relied – in part – on *eBay*, emphasizing that applications for interlocutory injunctions should be examined with a degree of circumspection.[53]

41. The Court declined to grant the interim injunction in light *inter alia* of its likely impact on those reliant on access to the generic version of the drug.[54] The Court had regard to the degree of harm to the public, the fact that it is absolute in nature and that the chances of improvement of life expectancy and of recovery in some cases would be 'snuffed out altogether'. The Court was not deterred by a lack of empirical material or statistical method by which it could deduce the number of people who would be affected. The Court found that whereas the damage or injury to the plaintiff could be assessed in monetary terms for purposes of the interim phase, the injury to the public is not only uncompensatable but irreparable.

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[52] 2008 (37) PTC 71 (Del); 148 (2008) DLT 598; MIPR 2008 (2) 35.
[53] Ibid at paragraph 63.
[54] *F. Hoffmann-La Roche*, above note 52 at paragraphs 85 and 86.

42. On appeal a two-judge bench of the same division upheld the original decision, noting that each matter must be decided on a case-by-case basis and that different factors may arise in each case. The appeal court considered the nature of the patent as well as the fact that the defendants had raised a credible challenge to its validity.[55] A petition for special leave to appeal to the Supreme Court was denied.

43. The decisions of *Novartis AG v Mehar Pharma* and *Franz Zaver Huemer v New Yash Engineers*, which predate *eBay*, are also instructive.[56]

44. In *Novartis AG*, the Bombay High Court considered the potential impact of an interim injunction on people given that the drug, an anti-cancer drug, would be supplied by the patentee through import whereas the defendant could manufacture the drug locally. The life-saving nature of the drug was a relevant consideration, as was the high demand for the drug in India. The consequences of unavailability, which were foreseeable, featured large in the assessment. The Court also considered the difference in price of the parties' products, considered to be of particular relevance at the interim relief stage.[57]

45. In *Franz Zaver Huemer*, the Delhi High Court considered public interest considerations – such as access to a life-saving drug, product quality and price – as central to a determination of the balance of convenience:[58]

[55] FAO (OS) 188/2008; 159 (2009) DLT 243; MIPR 2009 (2) 1 at paragraphs 81 – 84
[56] 2005 (30) PTC 160 Bom and AIR 1997 Delhi 79 respectively. They were referred to in *Hoffman-La Roche.*
[57] *Novartis AG*, above note 56 at paragraph 28.
[58] *Franz Zaver Huemer*, above note 56 at paragraph 33.

The proposed approach to protection of rights of people in need of medicines

46. We submit that when adjudicating applications for interim relief in pharmaceutical patent infringement cases, courts must ensure the public interest is not harmed by the grant of an interim interdict and that the rights of people in need of access to medicines are not unreasonably limited. The existing common law rules for the grant of an interim relief can readily accommodate this imperative under the rubric of the balance of convenience.

47. In line with existing principles, the onus of proof must rest on the party seeking interim relief to satisfy a court that its grant will not disservice the public interest or unreasonably limit the rights of people in need of access to medicines. If a court has insufficient evidence to satisfy itself that rights won't unreasonably be infringed, it must either refuse the relief or require further evidence. This general approach, we submit, would ensure that rights are protected in line with section 39(2) of the Constitution.

48. Although each case would have to be considered on its own facts, some considerations are likely to be relevant. For example:

    48.1. The nature of a patented product or process, including whether it is life-saving or otherwise important to public health.

    48.2. The practical consequences for people in need of medicines and doctors of the grant of an interdict and whether it would pose risks to the public health.

48.3. The impact of a grant of an interdict on those already reliant on the product alleged to infringe the patent, including whether lack of access for an interim period can harm people in need of access to medicines.

48.4. Whether the patentee in fact can service the need for a product.

48.5. The cost and availability of the disputed product bearing in mind that cost is a significant barrier to access, both in the public and private sectors and that many South Africans are reliant on access to health care services in the public sector.

48.6. Whether, and the extent to which, the availability of the disputed product in fact enhances access to medicines, whether in the public or private sector.

49. Factors relevant to the protection of the patent are also material. These will be many and varied but will *inter alia* require courts to consider contextually the extent to which the protection of the patent in South Africa is in fact necessary to create incentives for the development of similar products in the relevant field of technology and the nature of the patent in question.[59]

The evidence on record

50. The respondents have dealt in some detail with the issue. The appellants have failed to address the impact of the grant of interim relief on the public interest, simply adopting the attitude that it is not relevant. We submit that this is erroneous as the appellants in fact have an onus to demonstrate that the public interest will not unreasonably be harmed by the grant of an interim interdict and access to medicines

[59] See in this regard the Kennedy opinion in *eBay* where it was pointed out that patents are at times exercised less for their original purposes and more to extract high licencing fees. At page 1842.

will not be unreasonably limited. In our assessment, while there are some factors that are unclear, lives will probably be lost unnecessarily and the quality of life of others unnecessarily compromised if an interim interdict is granted in this case. But in any event, the appellants have not discharged their burden to satisfy the Court that the public interest won't be harmed and the rights of people with cancer won't be unreasonably be limited.

51. In an attempt to assist the Court to evaluate what evidence is available, we have prepared a table ('Annexure A') referring to some of the evidence on record that may be relevant to such rights, whether in favour of the appellants or the respondents.[60] In evaluating the evidence, however, it is important to bear in mind that the appellants were not purporting, in their affidavits, to address public interest concerns. The purpose for which they were adducing evidence that might, nevertheless, be regarded as relevant to the issue was either to deal with their claim that they cannot quantify their loss or to reply to the respondents when they dealt with the issue. In consequence, their evidence is in important respects insufficient, or raised for the first time in reply, placing the Court in an invidious position when making a decision that will inevitably have momentous consequences for people with cancer.

52. For example, an issue that may be relevant to access is the substitutability of docetaxel. This issue is dealt with by both parties insofar as it may be relevant to assessing the difficulty of quantifying damages. The Court is ultimately left in the

[60] The parties may wish to refer to other evidence we have not identified.

dark as to whether there are other medicines that can always be used in its place and are in fact accessible to those who need them. The respondents evidence reveals how important this enquiry is and say docetaxel is not (at least fully substitutable) but in the final result, the evidence remains equivocal on the issue of public interest and the rights of people living with cancer.

53. Another very important issue is whether docetaxel is readily available via the public health sector and affordable to those on medical aids. The appellants do not deal with this issue in their founding papers. The respondents raise the issue because they say that people with cancer will be unable to access docetaxel if an interim interdict is granted. In reply, for the first time, the appellants make very bold claims about the ease of access to docetaxel in both the private and the public sector. No facts are given as to how many people rely on the public sector and how many have access to medical aids, but judicial notice can probably be taken of the fact that a minority of the population have private medical aid in a country like South Africa. However, the appellants' remarks on access in both sectors are, in substance, in the nature of conclusions, responding to what they describe, in a troublingly dismissive fashion, as 'the emotive aspects surrounding the suffering of patients from cancer'.[61]

54. What the Court needs in order to perform its constitutional duties properly, is evidence from those with knowledge about how accessible docetaxel actually is in both the public and private sector and the extent to which it is supplied as a prescribed minimum benefit. This evidence is not provided and neither party

[61] Boshoff, vol 9, p.877, para 2.1.2

addresses all of the issues, at least adequately. The question of access to medicines and health services in the public sector is a fraught one. The appellants (in reply) are asking the court to assume that anyone living with cancer, who relies on public sector access will, without difficulty, access cancer treatment because the appellants supply the drug to the State via a tender.[62]

55. The evidence on private sector access through medical aids is similarly insufficient. But even the appellants' evidence shows that medical aid access will only benefit a few: nearly half of the people in the sample they considered have *express* financial oncology limits.[63] And it is simply not known what the real impact will be on those who are fortunate enough to have medical aid. While docetaxel is apparently provided in some circumstances as a prescribed minimum benefit,[64] the benefits are internally limited and depend on, amongst other things, the cancer in question and its treatability. These benefits are designed to provide a minimum level of care, not comprehensive treatment and the Court has not been told what is provided, when and for how long and, importantly, when docetaxel is not provided as a prescribed minimum benefit even if a doctors considers it appropriate to prescribe it.

56. We submit, in short, that there is insufficient evidence upon which the Court can conclude that the public interest will not be harmed because of the supply provided by appellants, in either the public or the private sectors.

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[62] Boshoff, vol 9, p.893, para 18.3

[63] Boshoff, vol 9, p. 893, para 19.5. Of their sample: "Only **43%** of the sample scheme lives have express financial oncology limits."

[64] The prescribed minimum benefits are contained in Annexure A to the Regulations to the Medical Schemes Act 1999

57. What is common cause is that the cost of Taxotere (and even Docetere) are significantly more expensive than respondents' product and that there are people who are currently using and will continue to need them. It seems that the only reason Docetere will be supplied at a lower price is if there is competition from respondents. It can reasonably be assumed that there are others living with cancer, or soon to be diagnosed, who will need cancer treatment and who will probably be unable to afford appellants' products and that even those with reasonable access to health care will not be able to obtain access. At the interim relief stage, we thus submit that on the limited evidence available to the Court, the public interest considerations weigh heavily in favour of ensuring ongoing access.

ALTERNATIVE REMEDIES

58. A central point of dispute in these proceedings is whether the appellants have an alternative satisfactory remedy, more particularly in damages. They say it is difficult to quantify damages and that they should not have to settle for the section 65(6) remedy as this is tantamount to forcing the grant of a licence.

59. The danger in accepting the appellants' submissions lies in the implicit suggestion that interdicts ought readily be granted in pharmaceutical patent infringement cases because of the inherent difficulty in proving damages and the desire to protect market exclusivity. Admittedly, the appellants' attitude is not novel.[65] Yet while this approach may reflect historical practice, as Harms DJP has himself opined extra-

[65] See Harms, supra, p 491.

curially, such practices must be revisited under the Constitution. Harms J writes in this regard: "*It is nevertheless foreseeable that in, say, pharmaceutical patent cases, where public health concerns or the constitutional right to health care arise, a court may have to consider whether or not to leave the rightholder to a damages claim.*"[66] We submit that this is so.

60. As set out above, developments in the US and India have affirmed the importance, in each case, of assessing whether the requirements for an interdict have been met, which in turn requires a consideration of all relevant factors including the public interest. The same is true in South Africa. The calculus, we submit, must always depend on the facts of the case. It cannot lightly be assumed that difficulties proving damages will preclude their adequate assessment. In *casu*, the patent is due to expire very shortly making the quantification of any damages for breach apparently easy.[67]

61. In short, where the rights of people who need access to medicines will be adversely affected by the grant of an interdict but harm to the patentee (even if only during the interim period) can be adequately compensated by a damages award in due course, no interim interdict ought to be granted.

CONCLUSION

62. We have set out the legal principles deriving from the Constitution that we submit are relevant to the grant or refusal of an interim interdict in context of alleged patent

[66] Id.
[67] Note that Indian Courts will require respondents to keep relevant records and submit them to court.

infringement proceedings. At the heart of the issue is the need for the Court to balance competing rights, a discretionary task that assumes particular importance in a country like South Africa where so many people are unable to access to health care and medicines. As a Kenyan Court recently held, albeit in a different context, "*While such intellectual property rights should be protected, where there is the likelihood, as in this case, that their protection will put in jeopardy fundamental rights such as the right to life of others, … they must give way to the fundamental rights of citizens …*"[68]

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[68] Supra at para 86.

ANNEXURE A

NATURE OF EVIDENCE	REFERENCES TO THE RECORD
Pricing and relative cost of parties' products	Boshoff, vol 2, p 132, para 7.1; De Jonge, vol 5, p 493, para 141 and p 436, para 23.1; Boshoff (reply), vol 9, p888, para 15.5 and new evidence on appeal. See too De Jonge, vol 5, p469,para75/6 re high cost of Taxotere. On Docetere price, see Boshoff, p 88, para 15.5 and new evidence.
Expense of oncology treatment	Raats, vol 7, p. 650, para 7 (Reply?) Boshoff, vol 9, p 888, para 15.5
The range of cancers treated	Boshoff, vol 2, p. 132, para 7.4 De Jonge, vol 5, p. 434, para 20 Raats, vol 7, p. 652, para 14
Extent of substitutability	Boshoff, vol 2, p 133, 7.5 But compare Raats, vol 7, p. 652, paras 15 et seq Boshoff, reply, vol 9, p. 877, par 2 and p 894, para 19 (See too resp heads)
Effectiveness of drug in treating cancer and impact of the drug on lives	Kugel, Vol 1, p.14, para 12.1 Boshoff, Vol 2, p 122, para 3.1 De Jonge, vol 5, p. 435, para 22; p 440, para 26. Raats, vol 7, p 654, para 19 (Reply?)
Importance of early access to cancer treatments	De Jonge, vol 5, p 434 para 21, p. 440, para 26 Raats, vol 7, p. 654-5, paras 20 to 21 (Reply?)
Number of patients currently on treatment, market changes	Respondents' supplementary evidence, if admitted together with appellants' reply
Consequences of taking Cipla patients off their current treatment in due course	Boshoff, vol 2, p 135, para 7.9; De Jonge, Vol 5, p. 497, para 156-157.
Access to patented product in South Africa via medical aid or public health sector	Raats, vol 7, p. 650, para 8 to 11 Boshoff, vol 9, p 877, para 2.1.2; p. 893, para 18.2, 18.3, 18.5 (General statements on med aids and public health access in reply)
Expiry of Docetaxel patent 2007. Access dependant on other patents	Kugel, vol 1, p. 14, para 12.2
Expiry Taxotere patent Nov 2013	Boshoff, vol 2, p. 122, para 3.2
Global Taxotere sales / R&D info 2010 Taxotere SA sales 2010 Taxotere global sales	Kugel, vol 1, p.15 para13.2 &p16-18, para 14; De Jonge, vol 5, p 472, para 85.1; De Jonge, vol 5, p 472-5, paras 84-7; Kugel (reply) vol 8, p 864, para 35. Boshoff, vol 2, p. 123, para 4.2.
Limited relevance of current SA market to relevant innovation costs	Kugel, vol 1, p 15, para 13.2 Boshoff, vol 2, p. 126, para 5.4; De Jonge vol 5, p 473, para 85.2-85.8; Kugel (reply), p 864, para 35; De Jonge, vol 5, p 475, para 86. Kugel (reply) vol 8, p 865, para 36
Allegations by CIPLA that Taxotere patent is used to maintain monopoly in Docetaxel	De Jonge, vol 5, p. 436, para 23.2; p 503, para 169 (Reply, generally Boshoff in reply – unclear?) Boshoff, new evidence, para 4.7 (on launch of Docetere)